CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Proposed Grant Awards

February 21, 2019

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE

FROM: JAMES WILLSON, M.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH FY2019 REVIEW CYCLE 1; AND RECRUITMENT AWARD RECOMMENDATIONS FY2019, CYCLE 19.4, 19.5 AND 19.6.

DATE: FEBRUARY 21, 2019

The Scientific Review Committee (SRC) and Program Integration Committee (PIC) recommendations for FY2019 review cycle 1 and recruitment cycles 19.4, 19.5 and 19.6 include **42** awards from seven grant mechanisms totaling **$52,856,653**. Please note that application RP190135 was recommended by the SRC; however, the application was subsequently withdrawn by the applicant. Note applications are ranked by overall score.

Due to SRC recommendations which exceeded the budgeted allocation to fund Academic Research Program awards for the second quarter of 2019, PIC recommended to defer action on applications recommended by the SRC with overall scores of 3.0 and higher.

Table 1:

Grant Mechanism	Program Integration Committee Recommendations	
	Awards	Funding
Individual Investigator Research Awards	23	$20,623,861
Individual Investigator Research Awards for Childhood and Adolescent Cancers	5	$5,968,636
Individual Investigator Research Awards for Computational Biology	1	$885,185
Individual Investigator Research Awards for Clinical Translation	4	$7,488,820
Individual Investigator Research Awards for Prevention and Early Detection	3	$3,890,151
Recruitment of Rising Stars	1	$4,000,000
Recruitment of First-Time, Tenure Track Faculty Members	5	$10,000,000
Total	**42**	**$52,856,653**

Program Priorities Addressed:
The applications proposed to the Program Integration Committee for funding address the following Academic Research Program Priorities: recruitment of outstanding cancer researchers to Texas, a broad range of innovative, investigator-initiated research projects, computational biology and analytic methods, disparities, childhood cancers, hepatocellular cancer and implementation research. The program priorities addressed by the proposed slate of awards are displayed in Table 2 and Attachment 1.

Table 2

Program Priorities Addressed by Grant Recommendations		
# Awards*	**Program Priorities**	**Funding***
6	Recruitment of outstanding cancer researchers to Texas	$14,000,000
36	A broad range of innovative, investigator-initiated research projects	$38,856,653
2	Computational biology and analytic methods	$1,782,077
8	Childhood Cancers	$9,859,353
6	Disparities	$7,959,907
1	Hepatocellular Cancer	$2,400,000
1	Implementation Research	$1,499,527
*Some grant awards address more than one program priority and are double counted.		

1.Individual Investigator Research Awards (RFA R-19.1 IIRA) Slate

Peer Review Recommendations:
The Scientific Review Council recommended 29 Individual Investigator Research Awards (IIRA) totaling $26,021,344. Due to the limits of funding for Fiscal Year 2019, the Academic Research Program recommends funding 23 IIRAs totaling $20,623,861 and deferring 6 IIRAs with overall scores of 3.0 or higher totaling $5,397,483 to August 2019 should funds be available.

Purpose of Individual Investigator Research Awards:
Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications are accepted.

Individual Investigator Research Awards Funding Levels:
Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

Table 3: Individual Investigator Research Awards Recommended for Funding

ID	Award Type	Meeting Overall Score	Application Title	PI	PI Organization	Rec. Budget	Priority Met*
RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000	
RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892	Computational Biology
RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433	
RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000	
RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000	
RP190398	IIRA	**2.0**	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566	
RP190019	IIRA	**2.0**	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000	
RP190278	IIRA	**2.0**	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000	
RP190192	IIRA	**2.1**	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000	Disparities
RP190236	IIRA	**2.1**	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397	
RP190256	IIRA	**2.4**	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992	Childhood Cancers
RP190301	IIRA	**2.4**	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000	
RP190077	IIRA	**2.4**	Molecular Action of Phospho-BRD4–Targeting Compounds in Breast Cancer	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	$864,000**	Disparities
RP190435	IIRA	**2.4**	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000	
RP190295	IIRA	**2.4**	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***	

ID	Award Type	Meeting Overall Score	Application Title	PI	PI Organization	Rec. Budget	Priority Met*
RP190326	IIRA	**2.4**	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000	
RP190218	IIRA	**2.5**	Deciphering the Underlying Biology and Translational Relevance of PD-L2	Curran, Michael A	The University of Texas M. D. Anderson Cancer Center	$900,000	
RP190252	IIRA	**2.5**	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000	
RP190029	IIRA	**2.7**	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000	Disparities
RP190131	IIRA	**2.7**	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907	Disparities
RP190235	IIRA	**2.8**	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747	
RP190454	IIRA	**2.9**	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000	
RP190211	IIRA	**2.9**	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927	

* All Individual Investigator Research projects address the "A broad range of innovative, investigator-initiated research projects"

** RP190077 SRC recommended funding for 2 of the 3 aims. Budget recorded reflects reduction, which was approved by SRC

*** RP190295 SRC recommended requiring 10% effort for PI for funding

2. Individual Investigator Research Awards for Cancer in Children and Adolescents (RFA R-19.1 IIRACCA) Slate

Peer Review Recommendations:
The Scientific Review Council recommended 7 Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), totaling $7,889,942. Due to the limits of funding for Fiscal Year 2019, the Academic Research Program recommends funding 5 IIRACAs totaling $5,968,636 and deferring 2 IIRACCAs with overall scores of 3.0 and higher totaling $1,921,306 to August 2019 should funds be available

Purpose of Individual Investigator Research Awards for Cancer in Children and Adolescents:
Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.

Individual Investigator Research Awards for Cancer in Children and Adolescents Funding Levels:
Up to $300,000 per year. Applicants that plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

Table 5: Individual Investigator Research Awards for Cancer in Children and Adolescents

ID	Award Type	Meeting Overall Score	Application Title	PI	PI Organization	Rec. Budget	Priority Met*
RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction in Childhood Cancer Survivors	Noel, Cory V	Baylor College of Medicine	$1,192,412	Childhood Cancers
RP190132	IIRACCA	**2.5**	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006	Childhood Cancers
RP190385	IIRACCA	**2.6**	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000	Childhood Cancers
RP190002	IIRACCA	**2.8**	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218	Childhood Cancers
RP190233	IIRACCA	**2.8**	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000	Childhood Cancers

* All Individual Investigator Research projects address the "A broad range of innovative, investigator-initiated research projects" priority.

3. Individual Investigator Research Awards for Computational Biology (RFA R-19.1 IIRACB) Slate

Peer Review Recommendations:
The Scientific Review Council recommended 3 Individual Investigator Research Award for Computational Biology (IIRACB), totaling $2,677,342. Due to the limits of funding for Fiscal Year 2019, the Academic Research Program recommends funding 1 IIRACB totaling $885,185 and deferring 2 IIRACB with overall scores of 3.0 and higher totaling $1,792,157 to August 2019 should funds be available

Purpose of Individual Investigator Research Awards for Computational Biology:
Supports applications for innovative mathematical or computational research projects addressing questions that will advance our knowledge in any aspect of cancer. Areas of interest include data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging or genomic, proteomic, and metabolomic databases; descriptive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions and use of artificial intelligence approaches to build new tools for mining cancer research and treatment databases.

Individual Investigator Research Awards for Computational Biology Funding Levels:
Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

Table 7: Individual Investigator Research Awards for Computational Biology Recommended for Funding

ID	Award Type	Meeting Overall Score	Application Title	PI	PI Organization	Rec. Budget	Priority Met*
RP190107	IIRACB	**2.3**	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185	Computational Biology

* All Individual Investigator Research projects address the "A broad range of innovative, investigator-initiated research projects" priority.

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4. Individual Investigator Research Awards for Clinical Translation (RFA R-19.1 IIRACT) SLATE

Peer Review Recommendations:
The Scientific Review Council recommended 5 Individual Investigator Research Awards for Clinical Translation; however, application RP190135 was subsequently withdrawn by the applicant. The Academic Research Program recommends funding 4 IIRACTs presented in Table 9 totaling $7,488,820.

Purpose of Individual Investigator Research Awards for Clinical Translation:
Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.

Individual Investigator Research Awards for Clinical Translation Funding Levels:
Up to $400,000 per year. Maximum duration: 3 years. Applicants that plan on conducting a clinical trial as part of the project may request up to $600,000 in total costs and a maximum duration of 4 years. Exceptions permitted if extremely well justified.

Table 9: Individual Investigator Research Awards for Clinical Translation Recommended for Funding

ID	Award Type	Meeting Overall Score	Application Title	PI	PI Organization	Rec. Budget	Priority Met*
RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252	Childhood Cancers
RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577	
RP190160	IIRACT	**2.2**	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000	Hepato-cellular Cancer; Disparities
RP190360	IIRACT	**2.6**	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991	

* All Individual Investigator Research projects address the "A broad range of innovative, investigator-initiated research projects" priority.

5. Individual Investigator Research Awards for Prevention and Early Detection (RFA R-19.1 IIRAP) SLATE

Peer Review Recommendations:
The Scientific Review Council recommended 3 Individual Investigator Research Award for Prevention and Early Detection, totaling $3,890,151. The Academic Research Program recommends funding all 3 IIRAPs as presented in Table 10 totaling $3,890,151.

Purpose of Individual Investigator Research Awards for Prevention and Early Detection:
Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Research may be laboratory-, clinical-, or population- based, and may include behavioral/intervention, dissemination or health services/outcomes research to reduce cancer incidence or promote early detection. Competitive renewal applications accepted.

Individual Investigator Research Awards for Prevention and Early Detection Funding Levels:
Up to of $300,000 per year for laboratory and clinical research; Up to $500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.

Table 10: Individual Investigator Research Awards for Prevention and Early Detection Recommended for Funding

ID	Award Type	Meeting Overall Score	Application Title	PI	PI Organization	Rec. Budget	Priority Met*
RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473	Childhood Cancers
RP190279	IIRAP	**2.2**	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung Carcinogenesis by Omega-3 Fatty Acids	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151	
RP190210	IIRAP	**2.5**	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527	Implementation Research

* All Individual Investigator Research projects address the "A broad range of innovative, investigator-initiated research projects" priority.

4. RECRUITMENT OF RISING STARS SLATE
FY19.4, FY19.5 and FY19.6

Peer Review Recommendations
The applications were evaluated and scored by the Scientific Review Council (SRC) to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of Recruitment of Rising Stars Awards:
The aim is to recruit outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.

Funding levels for Recruitment of Rising Stars Awards:
Up to $4 million over a period of 5 years.

Recommended Awards:
One Recruitment of Rising Stars grant application was submitted and was recommended by the Scientific Review Council for a Rising Stars Award.

RR190027
Candidate: Joshi Alumkal, M.D.
Funding Mechanism: Recruitment of Rising Stars
Applicant Organization: The University of Texas Southwestern Medical Center
Original Organization of Nominee: Oregon Health & Science University
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **2.0**
Recommended Total Budget Award and Duration: $4,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:
Joshi Alumkal, M.D., is a physician scientist being recruited as a Rising Star to UT Southwestern where he is expected to lead a program in genitourinary cancer research. He is currently an associate professor at Oregon Health & Science University where he leads an NCI funded research laboratory focused on androgen resistant prostate cancer and has an active clinical practice focused on genitourinary cancers. He has made important discoveries related to molecular mechanisms of castrate resistant prostate cancer and enjoys international recognition for his studies on neuroendocrine prostate cancers.

5. RECRUITMENT FIRST-TIME TENURE TRACK FACULTY MEMBERS SLATE FY19.4, FY19.5 and FY19.6

Peer Review Recommendations
The applications were evaluated and scored by the Scientific Review Council to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of First Time Tenure Track Faculty Recruitment
The aim is to recruit and support very promising emerging investigators, pursuing their first faculty appointment in Texas, who can make outstanding contributions to the field of cancer research.

Funding levels for First Time Tenure Track Faculty Members Recruitment
Up to $2 million over a period of up to 5 years.

Recommended Projects:
Out of seven First-Time Tenure Track Faculty Members applications submitted, the Scientific Review Council recommended five candidates for awards.

Below is a listing of the candidates with their associated expertise.

RR190023
Candidate: Uri Ben-David, Ph.D.
Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member
Applicant Organization: The University of Texas M. D. Anderson Cancer Center
Original Organization of Nominee: Broad Institute of Harvard and MIT
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **1.0**
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:
Uri Ben-David, Ph.D., is a cancer biologist being recruited as a First-Time, Tenure-Track faculty member to join M. D. Anderson from a postdoctoral fellowship at the Broad Institute. He has been highly productive and innovative at each stage of his career and proposes a cutting-edge approach to targeting aneuploidy (presence of an abnormal number of chromosomes in a cell) that reviewers found to be creative and important.

RR190025
Candidate: Julian West, Ph.D.
Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member
Applicant Organization: Rice University
Original Organization of Nominee: California Institute of Technology
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]:**1.6**
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:
Julian West, Ph.D. is a synthetic organic chemist being recruited as a First-Time, Tenure-Track faculty member to join Rice University having completed training at Princeton and Caltech. Rice will provide an exceptional environment for Dr. West to continue his highly innovative and impactful drug development research that will be complemented by plans for cancer focused interactions with investigators in the Texas Medical Center

RR190020
Candidate: Sangeetha Reddy, M.D.
Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member
Applicant Organization: The University of Texas Southwestern Medical Center
Original Organization of Nominee: The University of Texas M. D. Anderson Cancer Center
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **2.0**
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas; Disparities.

Description:
Sangeetha Reddy, M.D., is a clinical investigator being recruited as a First-Time, Tenure-Track faculty member to UT Southwestern. She is currently a Research Instructor at the University of Texas MD Anderson Cancer Center where she did her fellowship training in adult oncology. At UTSW her research will focus on the clinical development of novel immune therapeutics for breast cancer. She will be mentored by CPRIT Established Investigators, Drs. Carlos Arteaga and Yang-Xin Fu, as well as CPRIT grantee and 2018 Breakthrough Awardee, Dr. Zhijian "James" Chen. Her research proposal is considered both innovative and novel and having potential to change the resistance of patients with breast cancer to immunotherapy.

RR190029
Candidate: Ravikanth Maddipati, M.D.
Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member
Applicant Organization: The University of Texas Southwestern Medical Center
Original Organization of Nominee: University of Pennsylvania
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **2.2**
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas.

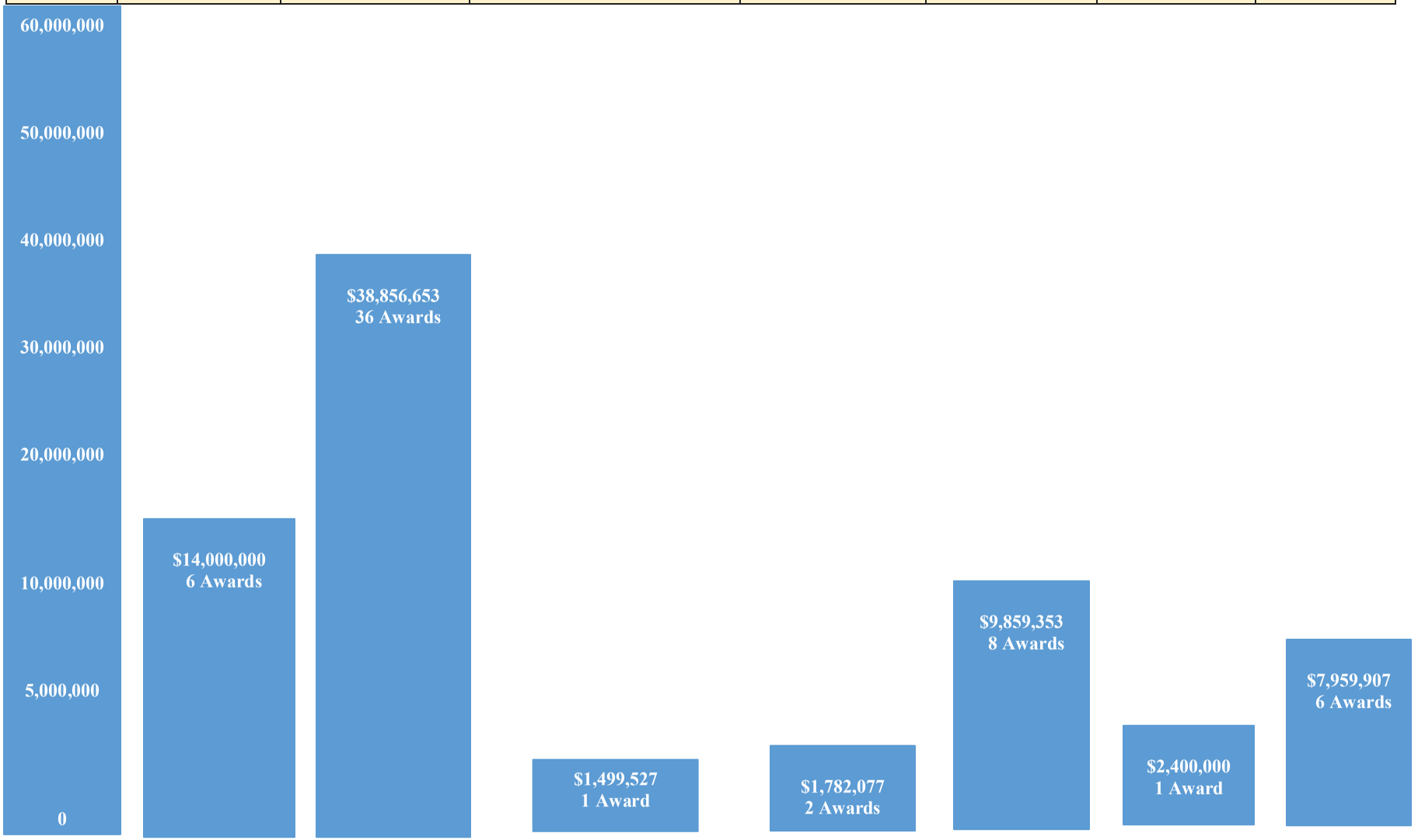
Description:
Ravikanth Maddipati, M.D., is a physician scientist being recruited as a First-Time, Tenure-Track faculty member to UT Southwestern. He trained at Massachusetts General Hospital and the University of Pennsylvania where he is currently appointed as an instructor. During his training he has made a significant contribution to understanding the heterogeneity of pancreatic cancer and plans to continue pancreatic cancer research at UTSW.

RR190021
Candidate: Di Zhao, Ph.D.
Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member
Applicant Organization: The University of Texas M. D. Anderson Cancer Center
Original Organization of Nominee: The University of Texas M. D. Anderson Cancer Center
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: **2.8**
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas.

Description:
Di Zhao, Ph.D., is being recruited as a first-time recruit to M. D. Anderson where she is currently working as a postdoctoral fellow in the laboratory of Ron DePinho. She had a strong publication record as a graduate student and postdoctoral trainee and has been awarded a NCI K99/R00 award. At M.D. Anderson she will continue research focused on prostate cancer.

Attachment #1

*Academic Research Program Priorities Addressed by Recommended Awards (*Some grant awards address more than one program priority and are double counted.)							
Scale	Recruitment of outstanding cancer researchers to Texas	A broad range of innovative, investigator-initiated research projects	Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions	Computational biology and analytic methods	Childhood Cancers	Hepatocellular Cancer	Population Disparities



- **Individual Investigator Research Awards**

  Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Cancer in Children and Adolescents**

  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Applicants that plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- **Individual Investigator Research Awards for Clinical Translation**

  Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.
  Award: Up to $400,000 per year. Maximum duration: 3 years. Applicants that plan on conducting a clinical trial as part of the project may request up to $600,000 in total costs and a maximum duration of 4 years. Exceptions permitted if extremely well justified.

- **Individual Investigator Research Awards for Computational Biology**
  Supports applications for innovative mathematical or computational research projects addressing questions that will advance our knowledge in any aspect of cancer. Areas of interest include data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging or genomic, proteomic, and metabolomic databases; descriptive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions and use of artificial intelligence approaches to build new tools for mining cancer research and treatment databases.
  Award: Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Prevention and Early Detection**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Research may be laboratory-, clinical-, or population- based, and may include behavioral/intervention, dissemination or health services/outcomes research to reduce cancer incidence or promote early detection. Competitive renewal applications accepted.
  Award: Up to of $300,000 per year for laboratory and clinical research; Up to $500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Recruitment of Established Investigators (RFA R-19-1 REI):**
  Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.
  Award: Up to $6 million over a period of five years.

- **Recruitment of Rising Stars (RFA R-19-1 RRS):**
  Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.
  Award: Up to $4 million over a period of five years.

- **Recruitment of First-Time Tenure Track Faculty Members (RFA R-19-1. RFT**):
  Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research.
  Award: Up to $2 million over a period up to five years.

LUDWIG CANCER RESEARCH

San Diego

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Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics
San Diego Branch

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January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on December 13, 2018 (REC Cycles 19.4 and 19.5), and January 17, 2019 (REC Cycle 19.6) to consider the applications submitted to CPRIT under the Recruitment of Rising Stars and Recruitment of First-Time Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended for all cycles is $14,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Candidate	Mechanism	Organization	Budget	Overall Score
1	RR190023	Uri Ben-David, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	1.0
2	RR190025	Julian West, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	Rice University	$2,000,000	1.6
3	RR190020	Sangeetha Reddy, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.0
4	RR190027	Joshi Alumkal, M.D.	Recruitment of Rising Stars	The University of Texas Southwestern Medical Center	$4,000,000	2.0
5	RR190029	Ravikanth Maddipati, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.2
6	RR190021	Di Zhao, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	2.8

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January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Individual Investigator Research Awards (IIRA), the Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), the Individual Investigator Research Awards for Clinical Translation (IIRACT), the Individual Investigator Research Awards for Computational Biology (IIRACB) and the Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on December 5, 2018 to consider the applications recommended by the peer review panels following their meetings that were held October 18, 2018 – October 25, 2018. Please note that RP190135 is included in the list below because it was recommended by the SRC; however, the application was subsequently withdrawn by the applicant.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The total amount for the applications recommended is $50,055,527.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
1	RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252
2	RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000
3	RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577
4	RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892
5	RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473
6	RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433
7	RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000
8	RP190135	IIRACT	**1.9**	Preventing Chemoradiation Bone Marrow Toxicities With FLT PET and SOD Mimics	McGuire, Sarah	The University of Texas Southwestern Medical Center	$2,087,928*
9	RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction in Childhood Cancer Survivors	Noel, Cory V	Baylor College of Medicine	$1,192,412
10	RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000

11	RP190398	IIRA	2.0	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566
12	RP190019	IIRA	2.0	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000
13	RP190278	IIRA	2.0	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000
14	RP190192	IIRA	2.1	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000
15	RP190236	IIRA	2.1	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397
16	RP190279	IIRAP	2.2	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung Carcinogenesis by Omega-3 Fatty Acids	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151
17	RP190160	IIRACT	2.2	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000
18	RP190107	IIRACB	2.3	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185
19	RP190256	IIRA	2.4	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992

20	RP190301	IIRA	2.4	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000
21	RP190077	IIRA	2.4	Molecular Action of Phospho-BRD4–Targeting Compounds in Breast Cancer	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	$864,000**
22	RP190435	IIRA	2.4	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000
23	RP190295	IIRA	2.4	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***
24	RP190326	IIRA	2.4	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000
25	RP190218	IIRA	2.5	Deciphering the Underlying Biology and Translational Relevance of PD-L2	Curran, Michael A	The University of Texas M. D. Anderson Cancer Center	$900,000
26	RP190252	IIRA	2.5	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000
27	RP190210	IIRAP	2.5	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527
28	RP190132	IIRACCA	2.5	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006
29	RP190385	IIRACCA	2.6	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000
30	RP190360	IIRACT	2.6	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991
31	RP190029	IIRA	2.7	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000

32	RP190131	IIRA	2.7	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907
33	RP190235	IIRA	2.8	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747
34	RP190002	IIRACCA	2.8	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218
35	RP190233	IIRACCA	2.8	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000
36	RP190454	IIRA	2.9	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000
37	RP190211	IIRA	2.9	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927
38	RP190251	IIRA	3.0	Defining and Enabling Delivery of microRNA and CRISPR Therapeutics for Hepatocellular Carcinoma (HCC)	Siegwart, Daniel J	The University of Texas Southwestern Medical Center	$900,000
39	RP190414	IIRACCA	3.1	Biochemical and Genetic Interrogation of EWSR1-FLI1 in Ewing Sarcoma	McFadden, David G	The University of Texas Southwestern Medical Center	$1,200,000
40	RP190287	IIRA	3.1	Regulation of CD8 T-Cell Responses in Antitumor Immunity	Sun, Shao-Cong	The University of Texas M. D. Anderson Cancer Center	$900,000
41	RP190421	IIRA	3.1	Structure-Based Drug Design of Inhibitors for a Breast Cancer Signature Kinase	Goldsmith, Elizabeth J	The University of Texas Southwestern Medical Center	$900,000
42	RP190346	IIRACB	3.3	Predicting Drug Response From Genomic Data Using Deep Learning Methods	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$892,157

43	RP190366	IIRA	3.3	Characterization and Optimization of Novel Allosteric KRAS Inhibitors	Gorfe, Alemayehu A	The University of Texas Health Science Center at Houston	$897,483
44	RP190208	IIRACB	3.4	Dissecting Cellular Heterogeneity of Bulk Tumors for Prediction of Overall Survival and Responsive Patients to Immunotherapy	Wang, Tao	The University of Texas Southwestern Medical Center	$900,000
45	RP190401	IIRACCA	3.4	A Mouse Model for Studying DIPG Initiation and Progression in the Pons	Xie, Zhigang	Texas A&M University System Health Science Center	$721,306
46	RP190358	IIRA	3.4	The Role of ZMYND8 in Breast Cancer Stem Cells and Tumor Progression	Luo, Weibo	The University of Texas Southwestern Medical Center	$900,000
47	RP190259	IIRA	3.4	Role of the N6-Methyladenosine (m6A) Writer METTL3/METTL14 in Cancer	Nam, Yunsun	The University of Texas Southwestern Medical Center	$900,000

*RP190135 – PI withdrew application POST- SRC recommendation and PRE-PIC meeting
**RP190077 reflects budget as reduced by the SRC. SRC recommended the removal of the 3rd aim.
*** RP190295 SRC recommended requiring 10% effort for PI in order to fund.

MEMORANDUM

TO:	CPRIT OVERSIGHT COMMITTEE
FROM:	REBECCA GARCIA, PH.D., CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	PREVENTION GRANT RECOMMENDATIONS – FY 2019 CYCLE 1
DATE:	FEBRUARY 7, 2019

Summary and Recommendation:
The Program Integration Committee (PIC) has completed its review of the recommendations forwarded by the Prevention Review Council (PRC). The PIC recommends awarding 7 projects for FY 2019 Cycle 1 totaling $12,328,462. The grant recommendations are presented in three (3) slates.

Number	Grant Type	Amount
2	*Tobacco Control and Lung Cancer Screening*	$2,999,827
4	*Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*	$9,028,669
1	*Dissemination of CPRIT-Funded Cancer Control Interventions*	$ 299,966

Background:
FY 2019 Cycle 1 (19.1)
CPRIT released four RFAs in June 2018 for the first review cycle of FY 2019. Twenty (20) prevention applications requesting $33,712,818 underwent peer review in Grapevine on December 11-12, 2018 and the programmatic review by the Prevention Review Council was conducted January 11, 2019. No applications were recommended for funding from submissions to the Evidence-based Cancer Prevention Services mechanism.

Program Priorities Addressed

All the recommended applications address one or more of the Prevention Program priorities. Some applications address more than one priority. See the attached chart for additional detail.

Number of Applications Addressing Priorities		
3	Prioritize populations disproportionately affected by cancer incidence, mortality or cancer risk prevalence	$ 8,787,554
6	Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence	$ 9,308,958
7	Prioritize underserved populations	$12,328,462

Prevention Program Slates

Tobacco Control and Lung Cancer Screening

Mechanism: This award mechanism seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.

Recommended projects (2): $2,999,827

Four (4) applications were submitted in this mechanism. Two (2) tobacco control and lung cancer screening projects are recommended.

Project Descriptions

PP190009	Expanding Tobacco Use Cessation in Northeast Texas	Prokhorov, Alexander V	The University of Texas M. D. Anderson Cancer Center	2.1	$1,499,956
CPRIT Priorities addressed: Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize underserved populations					

The Department of Behavioral Science at MD Anderson Cancer Center and The University of Texas Health Science Center at Tyler have partnered to increase tobacco cessation in the region. Eleven sites in Northeast Texas have agreed to participate. A patient referral process for implementation sites will be developed to maximize patient reach. MD Anderson Cancer Center tobacco treatment counselors will provide intensive care to patients referred. Staff at MD Anderson will be responsible for arranging participant follow-up calls to maximize quit attempts, tracking data about nicotine replacement use and cessation outcomes among participants until 6-month follow up. The evaluator, Dr. Yuan, Professor of Biostatistics will examine program outcomes such as provider training and cessation rates.

PP190027	Engaging Oral Health Providers for Evidence-Based Tobacco Cessation	Jones, Daniel L	Texas A&M University System Health Science Center	2.7	$1,499,871
CPRIT Priorities addressed: Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize underserved populations					

The proposed project will implement a new, comprehensive model of tobacco screening, referral, and treatment for dental patients in community clinics in Dallas County, and subsequently expand to partner sites in Denton and Amarillo. The revised clinical protocols and services will result in the availability of free screening, referral, counseling, and nicotine replacement therapy for dental patients, all at the same site. A second component of this proposal will deliver train-the-trainer workshops to dental hygiene professionals and students related to tobacco cessation. These trainings will be held in collaboration with dental hygiene programs located in East Texas, North Texas, and the Panhandle regions.

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

Mechanism:
This award mechanism seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Award: Maximum of $3M; Maximum duration of 36 months.

Recommended projects (4): $9,028,669

Seven (7) applications were submitted in this mechanism. Four (4) expansion of cancer prevention services to rural and medically underserved populations projects are recommended.

Project Descriptions

PP190004	Partnering With Schools and Clinics to Expand a Highly Successful HPV Vaccination Program for 9- to 17-Year-Olds From Medically Underserved Areas	Berenson, Abbey	The University of Texas Medical Branch at Galveston	1.5	$2,499,411
CPRIT Priorities addressed: Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize underserved populations					

This project expands the number of counties served from 2 to 25, including 13 that are both rural and medically underserved areas (MUAs.) The project provides onsite HPV vaccination services to adolescents in 8 schools located in 4 MUAs with very low vaccination rates. Vaccination services will be offered to patients 9–17 years of age from 25 counties who receive care in the original 3 pediatric clinics plus a family medicine clinic. The project will increase professional knowledge and program support through in-service presentations, educational lectures for groups, and one-to-one visits with providers.

PP190021	Access to Breast and Cervical Care for West Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	1.6	$2,430,998
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize underserved populations					

This project will expand breast and cervical cancer screening and prevention services to include South Plains (COG-2) and Central West Texas (COG-7) regions by replicating the successful ABC24WT project in the Panhandle (COG-1). The project includes an evidence-based “Train the Trainer” approach, culturally appropriate educational materials, community activists, and the “precede-proceed” models. ABC24WT will target women and their families via an educational and awareness campaign. County focused events will target women 40 and older for screening mammograms, 21-65 and older for screening Pap smears, and individuals 9-26 for HPV shots. Outreach and resource identification will be available to all income levels, but ethnic minorities and rural communities will be primary targets. The “no cost” services will be provided to uninsured/underinsured population who do not qualify for other indigent care funds.

PP190023	School-Based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuation and Expansion to Hidalgo County	Rodriguez, Ana M	The University of Texas Medical Branch at Galveston	1.9	$1,969,731
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize underserved populations					

This project aims to increase HPV vaccination uptake in Starr and Hidalgo Counties to match the NIS-Teen rates for Texas by implementing an educational campaign, a school-based HPV vaccination program, and providing support services (follow-up navigation, data collection, tracking, systems improvement). This collaboration between academic medical institutions, county health departments, and school districts employs school-based events (health fairs, vaccination days, back-to-school nights, meetings) and community-based education events (health department events, regional conferences, provider training sessions/workshops). This evidence-based intervention provides the HPV vaccine in an alternative setting (schools) and creates support for HPV vaccine by educating parents, school staff, and community healthcare providers.

PP190014	Expansion of Cervical Cancer Prevention Services to Medically Underserved Populations Through Patient Outreach, Navigation, and Provider Training/Telementoring	Schmeler, Kathleen M	The University of Texas M.D. Anderson Cancer Center	2.6	$2,128,529
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence; prioritize underserved populations					

This project expands the from the current 3 clinical sites in the RGV to 8 additional medically underserved areas (MUAs) in the RGV, Laredo, Northeast Texas, Bastrop and Brazoria counties. The comprehensive project will deliver public education on cervical cancer screening and HPV vaccination through community outreach and clinic inreach, coupled with patient navigation. Professional education for local providers will increase local capacity to deliver evidence-based cervical cancer prevention services. The expansion incorporates lessons learned and fills the demand from providers for training and Project Echo telementoring that will build capacity and provide access to care for rural and underserved populations.

Dissemination of CPRIT-Funded Cancer Control Interventions

Mechanism: This award mechanism seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
Award: Maximum of $300,000; Maximum duration of 24 months

Recommended projects (1): $299,966

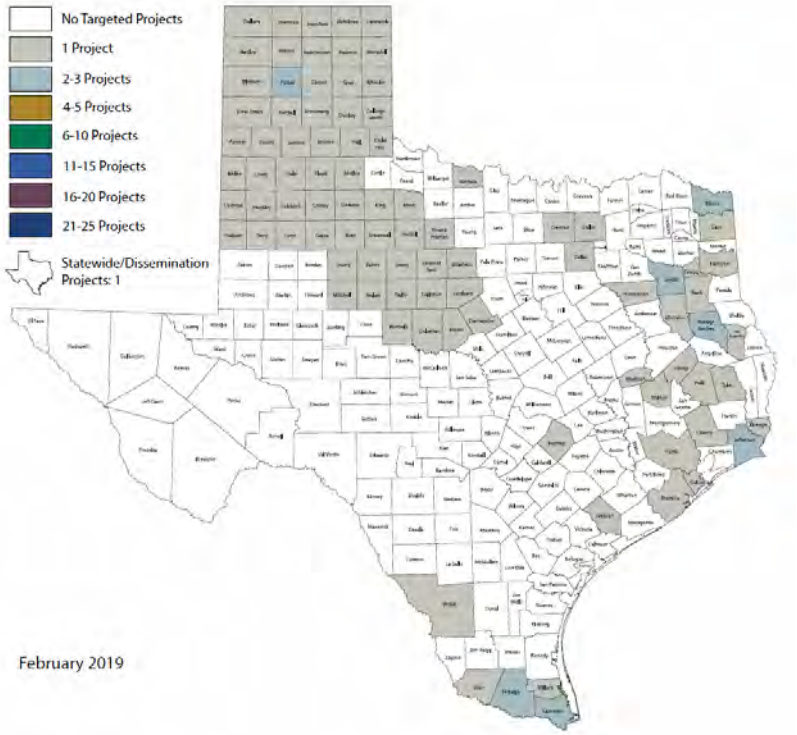
Two (2) applications were submitted in this mechanism. One (1) dissemination of CPRIT-funded cancer control interventions project is recommended.

Project Description

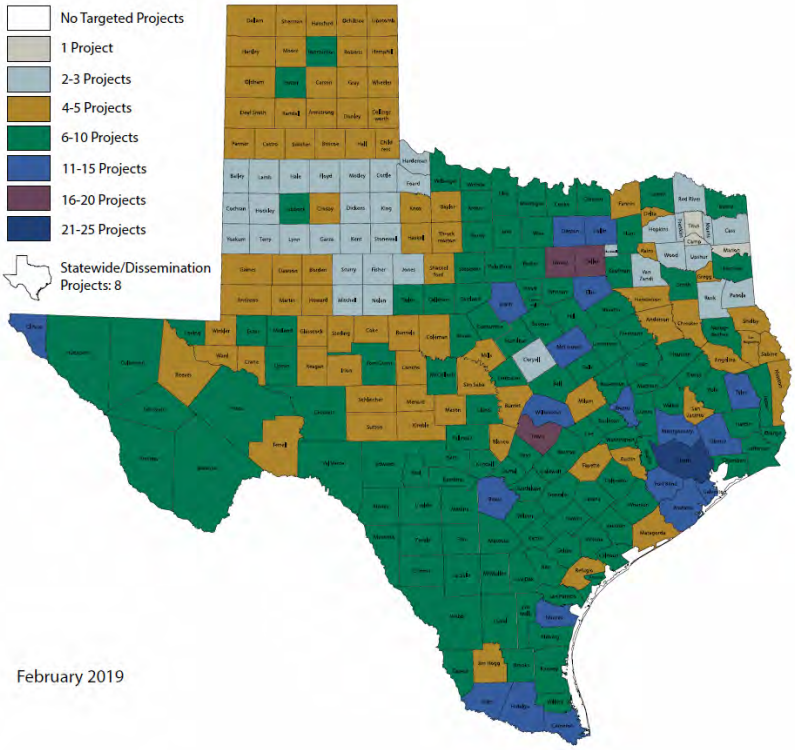
PP190041	Adolescent Vaccination Program: Online Decision Support for Adoption of Evidence-based HPV Vaccination Strategies by Texas Pediatric Clinics	Shegog, Ross	The University of Texas Health Science Center at Houston	2.0	$299,966
CPRIT Priorities addressed: Prioritize underserved populations					

This CPRIT dissemination project builds on a successful CPRIT-funded prevention collaborative program to develop and evaluate the web-based Adolescent Vaccination Program Implementation Tool (AVP-IT), designed to support the adoption, implementation, and maintenance of evidence-based HPV vaccination strategies into Texas pediatric clinics. The evidence-based strategies to increase HPV vaccination include assessment and feedback, electronic decision reminders, health care provider (HCP) cues, HCP training on message bundling and patient interaction, and direct education for patients. This bundled suite of evidence-based strategies was previously demonstrated effective in enhancing HPV vaccination rates. Rollout of the AVP in a large urban pediatric clinical network was associated with an increase in vaccination initiation rates from 53.9% in 2015 to 76.9% in 2017.

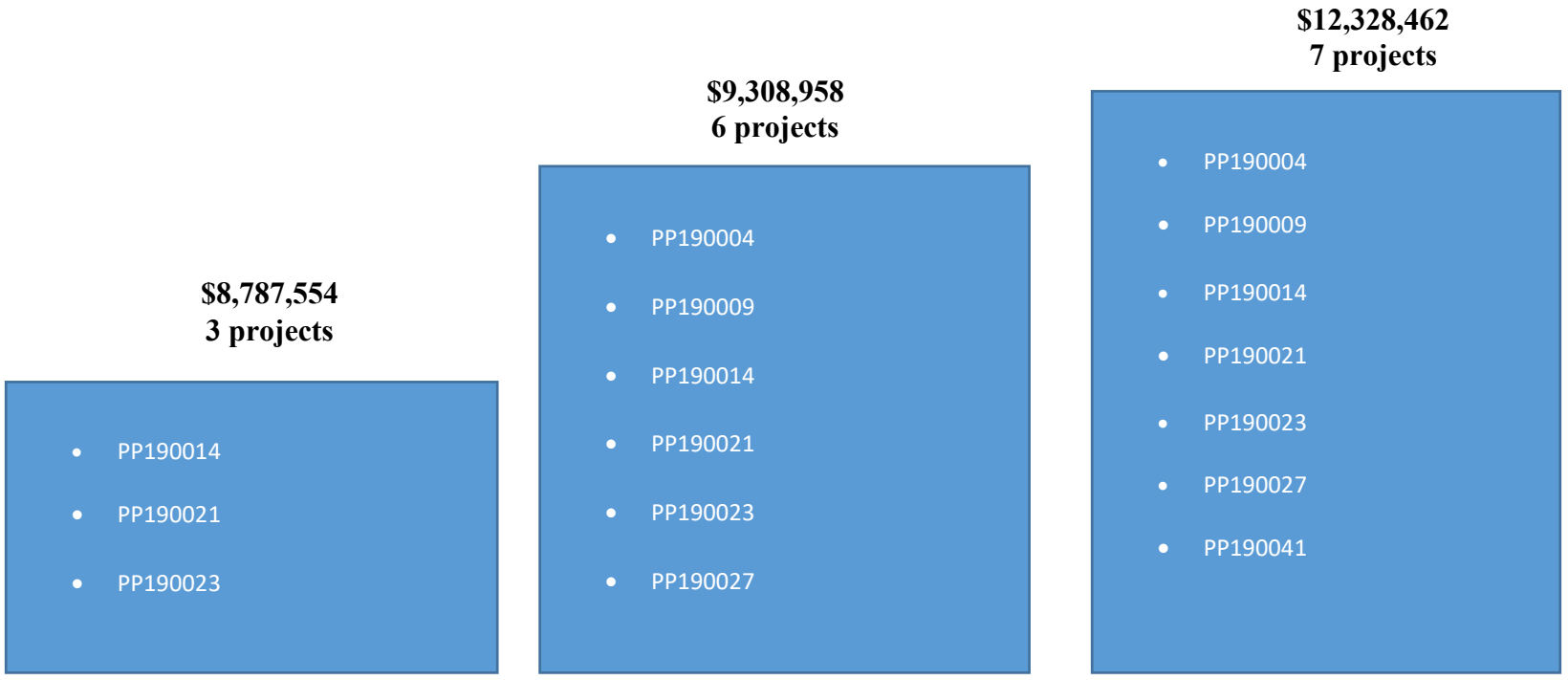
Counties of Residence of Populations Served by CPRIT Prevention Projects
7 Recommended Projects



Counties of Residence of Populations Served by CPRIT Prevention Active Projects + Recommended Projects
62 Active Projects + 7 Recommended Projects



Prevention Program Priorities Addressed by Recommended Awards February 21, 2019					
Prioritize populations disproportionately affected by cancer incidence, mortality or cancer risk prevalence		**Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence**		**Prioritize underserved populations**	



Note: Some grant awards address more than one program priority and will be double counted.

Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com
Via email to Will Montgomery assistant, Laura Blevins, lblevins@jw.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Roberts and Mr. Montgomery,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2019.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants.

The funding available for the fiscal year 2019 is $28,022,956. These recommended projects total $12,328,462.

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC continued to consider the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

Prevention Review Council Recommendations January 11, 2019											
Application ID	**Mechanism**	**Type**	**Application Title**	**PD**	**Organization**	**Total Requested Budget**	**Average Overall Score**	**Standard Deviation**	**Rank Order**	**Comments**	**Rec Budget**
PP190009	TCL	Resubmission	Expanding Tobacco Use Cessation in Northeast Texas	Prokhorov, Alexander V	The University of Texas M. D. Anderson Cancer Center	$1,499,956	2.1	0.6	1	Potential for Impact/Return on Investment and Type of	$1,499,956
PP190027	TCL	New	Engaging Oral Health Providers for Evidence-Based Tobacco Cessation	Jones, Daniel L	Texas A&M University System Health Science Center	$1,499,871	2.7	1.0	2	Potential for Impact/Return on Investment and Type of Program-Tobacco Control	$1,499,871
PP190004	EPS	Resubmission	Partnering with schools and clinics to expand a highly successful HPV vaccination program for 9-17 year olds from Medically Underserved Areas	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$2,499,411	1.5	0.5	3		$2,499,411
PP190021	EPS	New	Access to Breast and Cervical Care for west Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	$2,430,998	1.6	0.5	4		$2,430,998
PP190023	EPS	New	School-based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuation and Expansion to Hidalgo County	Rodriguez, Ana M	The University of Texas Medical Branch at Galveston	$1,969,731	1.9	0.3	5		$1,969,731
PP190014	EPS	New	Expansion of cervical cancer prevention services to medically underserved populations through patient outreach, navigation & provider training/telementoring	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	$2,128,529	2.6	0.8	6	Type of Program (EPS versus DI) and Potential for Impact/Return on Investment	$2,128,529
PP190041	DI	Resubmission	Adolescent Vaccination Program: Online Decision Support for Adoption of Evidence-based HPV Vaccination Strategies by Texas Pediatric Clinics	Shegog, Ross	The University of Texas Health Science Center at Houston	$299,966	2.0	0.0	7		$299,966

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER – REVIEW COUNCIL MEMBERS
DATE:	AUGUST 8, 2018

Waiver Request and Recommendation

I request that the Oversight Committee approve a fiscal year 2019 conflict of interest waiver for review council members pursuant to Health & Safety Code § 102.1062 "Exceptional Circumstances Requiring Participation." Unlike other conflict of interest waivers that the Oversight Committee has approved previously, this waiver is not granted for a specific conflict of interest or person. Instead, CPRIT intends to invoke this waiver as necessary to address the unusual scenario when a review council member has a conflict with a grant application that is part of the larger group of proposals that the review panel or review council must act upon (usually to recommend for awards). The waiver is necessary for a review council member to participate in the overall discussion and vote on the slate of award recommendations. This waiver is the same waiver the Oversight Committee approved for FY 2018.

Although it would be ideal to consider each instance individually before granting the conflict of interest waiver, a prospective waiver is necessary in this scenario given the timing of the review process and scheduled Oversight Committee meetings. It is unlikely that review panel schedules will align with Oversight Committee meeting dates such that CPRIT will be able to secure a conflict of interest waiver in time for the review council member to participate in the review process. However, adequate protections are in place that, together with the waiver's proposed limitations, mitigate the opportunity for factors other than merit and established criteria to influence review council members' decisions regarding the award of grant funds.

Background

Health & Safety Code § 102.1062 directs the Oversight Committee to adopt administrative rules governing the waiver of the conflict of interest requirements of the statute in exceptional circumstances. CPRIT's administrative rule § 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year. The rules require that a majority of the Oversight Committee members must vote to approve the waiver. CPRIT must report any approved waiver to the lieutenant governor, speaker of the

house of representatives, the governor, and the standing committees of each house of the legislature with primary jurisdiction over CPRIT matters.

The issue addressed by this waiver results from of the role review council members play in the review process. At the review panel level, the review council member chairs the review panel meeting. Occasionally, a review council member will identify a conflict of interest with an application assigned to the member's panel. If CPRIT is unable to reassign the application to a different panel, then the review council member follows the process set forth in CPRIT's conflict of interest rules and recuses himself or herself from any discussion, scoring, deliberation, or vote on the application. The proposed waiver will not change the review council member's responsibility to disclose the conflict or to recuse from the review of the application.

The difficulty arises when the review council member must lead the discussion, in his or her role as chair of the review panel, about the group of applications the panel recommends moving forward to the review council. If the application with which the review council member is in conflict advances as part of the group that scored well enough to move forward, the review council member's participation in the discussion on the group as a whole violates the member's agreement to not participate in "any discussion" of the conflicted application.

A similar challenge arises at the review council level. If the application with which the member is in conflict is part of the group considered by the review council, the conflict of interest rules prohibit the member from participating in the review council's discussion or vote on the group of awards. The review council member is unable to address questions about other applications heard by his or her panel due to his or her recusal from the process, potentially disadvantaging the other applications.

Exceptional Circumstances Requiring the Review Council Member's Participation

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. In this case, exceptional circumstances exist due to the necessity of the review council member's participation in the process to develop the overall award recommendation slates and the Oversight Committee should grant the proposed waiver. The limitations mitigate the potential for bias.

CPRIT's administrative rules require the Chief Compliance Officer to attend or designate an independent third party to attend peer review meetings and review council meetings when the panel discusses grant applications. The third-party observer must document that the reviewers follow CPRIT's grant review process consistently, including observing CPRIT's conflict of interest rules. The third-party observer will document any violation of this waiver in his or her written report, which CPRIT provides to the Oversight Committee prior to the vote on the award recommendations.

Proposed Waiver and Limitations

In granting the conflict of interest waiver, I recommend that CPRIT permit the review council member to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. The review council member must disclose any conflict in writing pursuant to the electronic grant management process CPRIT has in place.
2. The review council member must recuse himself or herself from participation in the review, discussion, scoring, deliberation, and vote on the specific grant(s) identified as the conflict.
3. When the review panel or review council takes up the grant applications as a group, the review council member may participate in the discussion and vote on the proposed awards, so long as the review council member does not advocate for or against the application that the member has identified as a conflict.
4. Whenever CPRIT invokes this waiver, the Chief Compliance Officer will provide information about the use of the waiver, including the name of the review council member and the identified conflict, in the Chief Compliance Officer's Certification report. I will also include this information in the CEO affidavit I submit for the grant award mechanism.

Due to the nature of the conflict or the type of review process, this conflict of interest waiver will not apply to following:

- When the review council member's conflict of interest is a conflict described by T.A.C. § 702.13(c); or
- When the review council is acting as the only review panel in the review process (e.g. CPRIT recruitment awards and prevention dissemination awards.)

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- CPRIT limits this waiver to review council members operating under the circumstances specified in this request.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	OVERSIGHT COMMITTEE MEMBERS
From:	KRISTEN DOYLE, INTERIM CHIEF PRODUCT DEVELOPMENT OFFICER
Subject:	FY 19.1 PRODUCT DEVELOPMENT GRANT RECOMMENDATIONS
Date:	FEBRUARY 7, 2019

Summary of Recommendation:

The Product Development Review Council (PDRC) and the Program Integration Committee (PIC) recommend that the Oversight Committee approve product development research grant awards for the following applicants: Hummingbird Bioscience, Allterum Therapeutics, Icell Kealex Therapeutics, Cell Medica, and Instapath. Table 1 reflects the ranked award recommendations, including the maximum recommended funding amounts and the overall evaluation scores for the five grant applications proposed for awards.

The PDRC and the PIC did not make any changes to the goals, timelines, or budgets for the five projects recommended for funding. However, execution of the award contracts for three companies are contingent upon the applicants taking the following actions:

- Allterum Therapeutics must complete the license agreement with the National Cancer Institute. In addition, CPRIT Product Development staff and IP counsel should review the documentation associated with the University of Maryland licensing agreement as outlined in the Vinson & Elkins IP Memorandum.

- Cell Medica must complete the recommendations set forth in the Vinson & Elkins IP Memorandum regarding patent coverage.

- Icell Kealex Therapeutics must resolve the IP and licensing issues outlined in the IP Diligence Memorandum from Baker Botts LLP.

Because these contract contingencies are related to intellectual property, CPRIT staff will work with outside IP counsel to review the companies' activities to satisfy the outstanding issues. The Chief Product Development Officer will notify the Oversight Committee when each company completes the items necessary for contract execution.

The PDRC and the PIC did not identify any contingencies associated with the awards to Hummingbird Bioscience or Instapath.

Table 1: 19.1 Review Cycle PDRC Award Recommendations

Rank	ID	Mech.	Company Name	Project	Score	Maximum Budget
1	DP190027	RELCO	Hummingbird Bioscience Pte Ltd	A First-in-Class Anti-VISTA Monoclonal Antibody for the Treatment of MDSC-Mediated Suppression of Antitumor Immunity in Solid Tumors and Lymphomas	2.0	$13,116,095
2	DP190025	SEED	Allterum Therapeutics, LLC	Preclinical Development of a Novel T-ALL Therapeutic Antibody	2.2	$2,912,313
3	DP190020	SEED	Icell Kealex Therapeutics LLC	Development of a Novel Oncolytic Vaccinia Virus Variant Suitable for Systemic Delivery	2.5	$3,000,000
4	DP190021	TXCO	Cell Medica	Off-the-Shelf CAR-NKT Cells for Treatment of Solid and Hematological Malignancy	3.1	$8,742,509
5	DP190018	SEED	Instapath Inc.	Rapid Pathology Evaluation System for Biopsies	2.2	$3,000,000
					Total	**$30,770,917**

Two 19.1 Review Cycle Applications Pending Final Decision

The PDRC elected not to make final award decisions for two pending applications, DP190041 and DP190046, considered during 19.1 review cycle. The PDRC requested additional information from the applicants to address issues raised during due diligence review. When the applicants provide the information, the PDRC will reconvene and issue final award decisions. We anticipate that the Oversight Committee will consider the PDRC award recommendations, if any, regarding these two pending proposals at either the May or August public meeting.

Background - FY 2019 Review Cycle 1

CPRIT released the 19.1 review cycle requests for applications (RFAs) on May 17, 2018. Applicants submitted 38 proposals, including 8 Relocation, 5 Texas Company and 25 Seed Company applications. CPRIT peer reviewers met September 24-25 (peer review panel screening teleconferences), October 23-26 (in-person presentations), and January 11, 14 and 22 (due diligence review teleconferences).

Of the 38 applications submitted in this cycle, CPRIT invited 17 applicants to present their applications in person to the review panels. Following the presentations, the review panels selected nine companies for due diligence review. After consideration of the due diligence reports, the PDRC recommended five applications for grant awards. Dr. Geltosky's noted in his letter to the PIC and the Oversight Committee that the PDRC's recommendation to fund these

five awards reflects 50+ hours of individual review and panel discussion of each proposal as well as the PDRC's review of the due diligence reports for each company.

The PIC met on February 7 and voted to recommend the PDRC's slate of proposed awards to the Oversight Committee.

Program Priorities Addressed by the Proposed Awards

The chart below reflects that all recommended applications address one or more of the Product Development Research Program priorities.

Applications Addressing Priorities*	Product Development Program Priorities	Award Amount per Priority*
5	Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies	$30,770,917
5	Funding projects addressing large or challenging unmet medical needs	$30,770,917
5	Investing in early stage projects where private capital is least available	$30,770,917
2	Stimulating commercialization of technologies developed at Texas institutions	$11,742,509
4	Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations	$22,028,408
5	Providing appropriate return on taxpayer investment	$30,770,917

*Some proposed grant awards address more than one program priority.

Mechanism of Support and Program Objectives

Proposals submitted in the 19.1 review cycle responded to one of three product development research RFAs. This is the first cycle that CPRIT released the Seed RFA.

- *Texas Company Product Development Research Award* (TEXCO)
  Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must headquarter in Texas.
  Award: Maximum amount $20M over 36 months

- *Relocation Company Research Award* (RELCO)

Supports early-stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must relocate to Texas upon receipt of award.
Award: Maximum amount $20M over 36 months

- *Seed Award for Product Development Research* (SEED)
  Supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award, and the Company Relocation Award. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Company applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award.
  Award: Maximum amount of $3M over 36 months.

CPRIT's Grant Award Contract and Risk Mitigation

Investing in early stage translational cancer research is inherently risky. Therapies that show promise in the lab and in animals may not make a measurable difference in humans or the treatment's side effects may be so severe as to not justify the benefits. Along with the increased risk of scientific failure, human studies are more expensive than laboratory and animal studies.

CPRIT addresses the risk associated with product development research awards by tying disbursement of grant funds to the grantee achieving specific project goals and objectives. The grant contract requires the company to report at least annually on its progress. To receive the next tranche of project funding, the grantee must show that it has accomplished all the goals and objectives for the previous project year. The company will only receive the entire approved award amount if it successfully achieves all project goals and objectives. Because contractual goals are usually associated with project milestones, such as receiving FDA approval for an Investigational New Drug filing or completing a clinical trial, achieving all agreed-upon goals also means that the project is making meaningful progress to becoming a treatment option.

Product Development Research Program Awards
Recommended by the PDRC and the PIC for FY 2019 Review Cycle

Hummingbird Bioscience Pte Ltd
Proposed Company Relocation Product Development Research Award

Summary of Recommendation

The PDRC and the PIC recommend that the Oversight Committee approve a Relocation Company Product Development Research Award to Hummingbird Bioscience for $13,116,095.

Hummingbird Bioscience, founded in 2014, develops novel therapeutic antibody-based drugs. The company has 20 employees in its laboratories in JLABS South San Francisco and in Singapore. If it receives a CPRIT award, the company commits to relocate to Texas to develop a new cancer therapy, HMBD-002-V4, for patients resistant to immuno-oncology (IO) drugs.

CPRIT Product Development Research Program Priorities Addressed

Hummingbird Bioscience's planned development of a novel cancer therapy designed for patients who are resistant to cancer IO drugs addresses a significant unmet clinical need. The proposed project addresses five Product Development Research Program Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, *i.e.* disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects where private capital is least available;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale Underlying Lead Program

FDA-approved IO drugs harnessing the power of the body's immune system to fight cancer have made rapid advances in treating patients who previously had very few options. This includes patients with melanoma, non-small cell lung cancer, kidney and bladder cancer and several others. However, as many as 70% of these patients develop resistance and their cancer progresses, and they are again without options.

HMBD-002-V4 is designed to treat one of the most important causes of resistance – a branch of the immune system called MDSC cells that switch off the cancer killing cells initially activated by the IO drugs. In preclinical studies, HMBD-002-V4 showed the ability to reverse resistance to IO therapies and to completely cure the cancer in some cases.

The CPRIT project aims to bring a new cancer therapy to patients. The team will manufacture clinical-grade material and apply to the FDA for an Investigational New Drug application that will allow HMBD-002-V4 to begin a Phase IA/B study in Texas. The company intends to confirm in the proposed trial that the drug is safe and to start looking for responses from patients who have become resistant to approved IO therapies and whose cancers have progressed.

Selected Reviewer Comments

- *There is a strong management team that understands drug development, which is reflected in a well-written proposal, realistic timelines, budget, and assessment of knowledge gaps addressing those appropriately with critical hires, consultants, and KOLs.*
- *The preclinical data package and CMC are solid and at stage to advance to regulatory submission and clinical development.*
- *It is a high-interest target to pharma and biotech, providing an opportunity of first in class and increases the likelihood to realize future funding, partnering and successful investor exit.*
- *The proposed budget is appropriate and realistic; the applicant took great care to detail projected expenses over the funding period, which do not appear excessive but realistic in order to achieve the key milestones.*
- *The proposed compound can address a significant unmet medical need, i.e., patients with cancer either refractory or resistant to current immune therapies.*
- *The product addresses a huge unmet medical need. A product such as this one could advance the I/O field to "the next level."*

Project Goals and Objectives

CPRIT will incorporate the following project goals and anticipated time for completion in Hummingbird's grant contract. A full list of the objectives is available in the application.

- Goal 1 (Y1/Q1-Y2/Q2):
  Validate Biomarkers in Humanized Mouse Models and Human Patient Samples

- Goal 2 (Y1/Q1–Y2/Q2):
  Complete Master Cell Bank development, Process/Formulation, Engineering/ Toxicology and Clinical Batch Production

- Goal 3 (Y1/Q4-Y2/Q2):
  Complete HMBD-002-V4 IND Enabling Studies

- Goal 4 (Y1/Q3-Y2/Q3):
  Complete IND submission, Initiate & Complete Phase IA & Phase 1B HMBD-002-V4 trial

- Goal 5: (Y1/Q1-Y1/Q4)
  Hummingbird Bioscience will Expand Operations in Texas, Hire Additional Personnel and Contract for Services with Texas Companies

Allterum Therapeutics, LLC
Proposed Seed Award for Product Development Research

Summary of Recommendation

The PDRC and the PIC recommend that the Oversight Committee approve a Seed Award for Product Development Research to Allterum Therapeutics, LLC, for $2,912,313.

Allterum Therapeutics, a Houston-based company, is developing a new drug for the treatment of pediatric T-cell acute lymphoblastic leukemia – a common form of childhood cancer. Although current treatments are effective for most children, approximately 20% of patients experience a recurrence of the disease. Allterum's drug is an antibody that is capable of more specifically targeting and killing cancer cells without the broad side effects typically observed with conventional therapies. Allterum addresses a major unmet medical need because the company expects the drug to be effective not only in children with recurring leukemia but to also to aid conventional chemotherapies when patients are first treated.

CPRIT Product Development Research Program Priorities Addressed

The project proposed by Allterum addresses five Product Development Research Program priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects where private capital is least available;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale Underlying Lead Program

Although acute lymphoblastic leukemia (ALL) is the most common pediatric leukemia, accounting for 26% of all childhood leukemia, it accounts for fewer than 6,000 new cases a year. Most patients have B-cell ALL, with T-cell ALL (T-ALL) accounting for only 15-20% of ALL patients. Unfortunately, given the small population of T-ALL patients, and the smaller number of patients with relapsed T-ALL (~120-150 cases each year) there has been no focus on targeted new therapies for relapsed T-ALL despite the clear unmet medical need. Allterum is developing a novel cancer therapeutic for relapsed T-ALL patients.

Selected Reviewer Comments

- *While this is a fairly small patient population, these children do not have many options left if current therapies fail. It should also be useful in treating adults with the same condition.*
- *[This proposal] focuses on an indication for which the target has been validated, using a standardized development strategy…that seems to be low risk, with an experienced management team that has generated INDs previously.*
- *Overall, although the market is very small, a breakthrough therapy to help children/young adults with recurrent/refractory T-ALL is worth investing in.*
- *The management team seems very well qualified considering the stage of development of the project.*
- *The company has presented a thorough competitive analysis from which their conclusions as to potential advantages of their product appear very plausible. Substantial familiarity with relevant regulatory aspects, including eligibility for a Rare Pediatric Disease Priority Voucher, is apparent.*

Project Goals and Objectives

CPRIT will incorporate the following project goals and anticipated time for completion in Allterum's grant contract. A full list of the objectives associated with each goal is available in the application.

- Goal 1 (Y1Q1/Q2):
  Complete Preclinical Efficacy, DMPK and Safety Studies

- Goal 2 (Y1Q2/Q3):
  Assay Development & Human Tissue Cross-Reactivity Studies

- Goal 3 (Y1Q4 – Y2Q1/Q4):
  Toxicology Testing in Animals

- Goal 4 (Y2Q2/Q3 – Y3Q4):
  IND Package Submission & Initiation of GMP-Production

- Goal 5 (Y3Q4):
  Establishment of Phase I Protocol and Clinical Trial Sites

Icell Kealex Therapeutics LLC
Proposed Seed Award for Product Development Research

Summary of Recommendation

The PDRC and the PIC recommend that the Oversight Committee approve a Seed Award for Product Development Research to Icell Kealex Therapeutics LLC for $3,000,000.

Scientists from the Baylor College of Medicine founded Icell Kealex Therapeutics in 2015. The Houston-based company is developing an oncolytic virus designed to treat advanced solid tumors, including melanoma, breast cancer, colorectal cancer, pancreatic adenocarcinoma and ovarian cancer.

CPRIT Product Development Research Program Priorities Addressed

The project proposed by Icell Kealex addresses all six Product Development Research Program Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects where private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale Underlying Lead Program

Oncolytic viruses infect and kill tumor cells while leaving healthy cells unharmed, making them an exciting new area of cancer therapy. However, current oncolytic virus-based therapies have demonstrated some limitations.

The optimal route of delivery of oncolytic viruses – systemic intravenous injection – is significantly restricted by the immune response induced by the virus. Antibodies neutralize the virus by binding to it directly or by marking it for destruction by complement or by other immune cells. With each subsequent administration of the virus, the patient's immune response is faster and stronger, which restricts the ability of the virus to persist long enough to reach the tumor and eliminates possibility of redosing. A direct injection of the virus into the tumor overcomes this limitation, delivering the virus directly to the cancer cells. But this approach is not suitable for some tumors and does not account for cases when the tumor has metastasized.

Icell Kealex has developed a novel vaccinia virus engineered to overcome the limitations of traditional virus-based therapies. The proposed project explores a novel concept for cancer virus therapy targeting multiple types of solid tumors.

Selected Reviewer Comments

- *The team is experienced in the science and has already demonstrated expertise in generating the different components of the [technology]. I have confidence they can generate the final construct.*
- *The company has thoughtfully sought FDA advice on its development plan through a pre-pre-IND meeting. Much useful feedback was provided, and there appears to be a clear path to an IND.*
- *Considering development stages, there are no apparent major weaknesses in the application. On the contrary, this is a well-thought-through project based on sound and innovative science with significant potential to address unmet need.*
- *Based on its fundraising track record, raising required matching funds should not be an undue challenge. Other strengths of the application are the clarity and reasonableness of the proposed budget, the soundness of the competitive analysis, and the already-established master cell bank.*
- *…[T]he company seems to have appropriately experienced personnel for the stage of development of the project.*

Project Goals and Objectives

CPRIT will incorporate the following project goals and anticipated time for completion in Icell Kealex's grant contract. A full list of the objectives associated with each goal is available in the application.

- Goal 1 (Y1 Q1-2):
  Non-GMP level mFAP-TEA-VVNEV will be produced. Evaluate the FAP-TEA-VVNEV in vitro. NAb escape, T-cell activation and proliferation, oncolytic activity (direct killing by the virus; bystander killing by T cells of the tumor cells not infected by the virus), replicative capacity, and stromal destruction of human FAP-TEA-VVNEV will be tested using transformed cell cultures and standard immune assays. In vitro studies will be performed in our laboratory located in JLABS@TMC, in Houston, TX.

- Goal 2 (Y1 Q3 – Y2 Q2):
  Clinical grade FAP-TEA-VVNEV will be produced and evaluated as above.

- Goal 3 (Y2Q3-Y3Q2):
  Evaluate anti-tumor efficacy of FAP-TEA-VVNEV in vivo. FAP-TEA-VVNEV and control VVs will be administered intravenously to tumor bearing mice and the following will be compared: 1) Ability of the virus to find, replicate and spread within tumors in the preimmunized vs. the non-immunized mice; 2) Ab and T-cell responses against virus and against the FAP in the preimmunized vs. the non-immunized mice; 3) virus' ability to facilitate T-cell activation and infiltration into the tumors; 4) tumor killing efficiency of the virus.

- Goal 4 (Y2Q3-Y3Q2):
  Evaluate the safety of FAP-TEA-VVNEV in mouse models. FAP-TEA-VVNEV will be assessed with biodistribution (tissue histology and in vivo viral replication) and mouse survival. Mouse studies will be conducted @ Baylor College of Medicine and evaluated in our lab. Our proposal also takes advantage of the GMP facility of the Center for Cell and Gene Therapy @ Baylor College of Medicine, capable of producing clinical grade reagents including viruses and cell lines according to cGMP.

- Goal 5:
  Submit the IND and receive all necessary approvals.

Cell Medica
Proposed Texas Company Product Development Research Award

Summary of Recommendation

The PDRC and the PIC recommend that the Oversight Committee approve a Texas Company Product Development Research Award to Cell Medica for $8,742,509.

Cell Medica, Inc. established its U.S. headquarters in Houston when it received a CPRIT Product Development award totaling $15.6 million in 2012. The company has additional locations in London and Zurich. Cell Medica's initial CPRIT grant, to develop cellular therapies for the treatment of cancers associated with viral infections following bone marrow transplant, supported a key collaboration with Baylor College of Medicine, leading to the co-development of novel cancer therapies. Cell Medica will use the second CPRIT award to further a treatment approach that uses healthy donor immune cells modified to treat a variety of incurable tumors. Project funds will support Phase 1 and Phase 2 clinical trials conducted at Baylor College of Medicine and other Texas institutions to advance this novel therapy into humans.

CPRIT Product Development Research Program Priorities Addressed

The project proposed by Cell Medica addresses 5 of the 6 Product Development Program Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects where private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale Underlying Lead Program

The proposed $8,742,509 award to Cell Medica, Inc. supports the development of a novel off-the-shelf chimeric antigen receptor (CAR) natural killer T cell (NKT) therapy. Cell Medica's novel approach uses healthy donor immune cells (off-the-shelf) modified to treat a variety of incurable tumors. The proposed CPRIT grant will support Phase 1 and 2 clinical studies conducted at Baylor College of Medicine and other Texas institutions to advance this novel therapy into humans. Cell Medica also proposes to develop new CAR NKT products for additional indications at their Houston facility.

Current CAR T cell products are autologous; the patient's own isolated T cells are modified by CARs targeting the patient's cancer, which is then administered to the patient. While effective for some blood cancers, such as lymphoma and leukemia, these products have several issues.

Patient response rates need improvement, even in lymphoma, and safety is problematic. Time needed to modify a sick patient's cells, often taking weeks, is too long and some patients do not generate enough cells for treatment. Also, CAR T cells are less effective for solid tumors because the tumor itself inactivates the CAR T cells.

Cell Medica's off-the-shelf CAR NKT therapy uses NKT cells from healthy donors, which are immediately available to sick patients. These donor NKT cells, when given to a patient, do not attack a patient's cells, so graft vs. host disease (GVHD) issues are not a limitation. The donor NKT cells also resist attack by the patient's immune cells. Engineered to express CARs and other critical proteins, the donor NKT cells will target the tumor, survive the suppressive tumor environment, and laboratory studies show that these CAR NKT cells kill the tumor.

Selected Reviewer Comments

- *This is a creative approach to allogenic, off-the-shelf CAR-NKT therapy. There are lots of potential advantages over autologous approaches. These are highly engineered cells to overcome GVHD and to boost antitumor activity of the infused cells. There are lots of moving parts, but this company seems to have the expertise to pull this off. The company has an excellent track record with CPRIT and is well capitalized.*
- *This is a very strong application from one of the foremost pioneering research groups in the field of adoptive NKT cell transfer for cancer treatment.*
- *A strength of the company is the team, including the folks at Baylor who are experts in cell-based therapies.*
- *In summary, this is a very strong application by a highly competent team, for a product with much important clinical potential.*

Project Goals and Objectives

CPRIT will incorporate the following project goals and anticipated time for completion in Cell Medica's grant contract. A full list of the objectives associated with each goal is available in the application.

- Goal 1 (Y1Q1-Y3Q4):
  Complete Phase 1 Study in Patients with Relapsed/Refractory (R/R) CD19 Positive Non-Hodgkin Lymphoma (NHL) This will be a first in human study of CD19-CAR NKT cells (CMD-502) performed at the Baylor College of Medicine (Baylor) in Houston, TX. GMP manufacturing for this study will also be performed at Baylor. Milestone 1: Trial recruitment started Y1/Q1 Milestone 2: Two dose levels treated Y1/Q4

- Goal 2 (Y1Q1-Y3Q4):
  Develop Manufacturing Processes and Test Methods to Support Phase 2 Milestone: Tech transfer to Cell Medica GMP manufacturing Y2/Q2

- Goal 3 (Y1Q3-Y3Q4):
  Initiate and Complete Enrollment in Multicenter, Phase 2a Study of CD19 CAR NKT cells in Adult Patients with Relapsed/Refractory (R/R) Diffuse Large B Cell Lymphoma and Acute Lymphoid Leukemia. This will be a phase 2a study conducted at multiple clinical sites, including multiple Texas sites. Milestone 1: US trial cleared to begin Y2/Q4 Milestone 2: 10 patients treated Y3/Q2

- Goal 4 (Y1Q1-Y3Q4):
  Discover and Validate New CARs for future allogeneic NKT Cell Products. Milestone: CAR NKTs for at least 2 tumor targets ready for in vivo testing Y2/Q4. The goal of this work stream is to discover new tumor targets and generate new CAR constructs that will address current limitations of autologous CAR cell products against both solid and hematologic tumors. In addition, we will develop analytical assays to support product development and immune monitoring of patients during the clinical trials.

Instapath, Inc.
Proposed Seed Award for Product Development Research

Summary of Recommendation

The PDRC and the PIC recommend that the Oversight Committee award a Seed Award for Product Development Research to Instapath, Inc. for $3,000,000.

Instapath, Inc. is a medical device startup that is developing a microscopy system that provides an exact picture of cancer biopsies within seconds, providing essential biopsy quality evaluation to ensure an accurate final diagnosis.

CPRIT Product Development Research Program Priorities Addressed

Instapath's proposed projects addresses five Product Development Research Program Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects where private capital is least available;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale Underlying Lead Program

Seven million biopsy procedures are performed annually to diagnose cancer or collect tumor tissue for personalized therapy. Yet, due to inadequate biopsy tumor content, one in five biopsy procedures must be repeated to confirm diagnosis, and thousands of patients cannot receive potentially life-saving therapies because of downstream test failures. If doctors can quickly determine that a sample is insufficient, then they can collect more tissue immediately. However, currently available tests are too slow and destructive and require dedicated personnel.

Instapath's technology re-envisions the way this testing is done. The company has developed an Automated Digital Pathology Lab (ADPL) imaging system that updates the traditional histology workflow, for the first time enabling users to go from the fresh sample directly to the histology image automatically and quickly. By making tissue adequacy testing fast, non-destructive, and fully automated, doctors can verify sample adequacy in less time with fewer personnel during the procedure, while there is still time to collect more tissue if needed. By producing images that can be reviewed remotely, the ADPL system may be transformative for the 92.52% of Texas counties that contain medically-underserved rural institutions without on-site pathologists. The ADPL system would allow for remote assessment and guidance of biopsy procedures,

empowering hospital systems in underserved communities to provide higher quality of care with limited personnel resources.

Selected Reviewer Comments

- *There is clear unmet clinical need with benefits to all stakeholders in the cancer diagnosis care pathway. Cost savings are realized via reduced OR time and human resource requirements. Improved care delivery is achieved by greater geographical reach due to remote review capabilities.*
- *The Strong technical credentials of the team are supplemented by seasoned business professionals with experience in commercializing medical technology.*
- *Instapath is proposing to commercialize a novel process for evaluating cancer biopsies, automated digital pathology lab, that will decrease both the time and the need for repeat biopsies. To accomplish this, the applicant proposes to develop a new platform for imaging, validate the results clinically, and submit the data to the FDA for clearance. The process proposes to allow the biopsy to go from fresh sample directly to the histology image in an automated and reproducible manner, does not require the existing degree of human resources, and would serve community hospitals as well as academic medical centers equally.*
- *The proposal, an automated digital pathology lab (ADPL) to deliver biopsy sample-to-image within 5 minutes of tissue removal, could be of significant importance for physicians requiring data to determine subsequent plan of actions and therapeutic interventions. The company has stated that over 7 million patients in the United States undergo biopsy procedures each year with 20% requiring repeat procedures due to inaccurate biopsy assessments*
- *This program also addresses the clear unmet medical need of potential benefit to underserved populations with an innovative concept using telemedicine.*
- *Development so far has benefitted from extensive user input.*

Project Goals and Objectives

CPRIT will incorporate the following project goals and anticipated time for completion in Instapath's grant contract. A full list of the objectives is available in the application.

Goal 1 (Y1Q1 – Y1Q4):
Design and development of alpha and beta ADPL prototypes, and pilot clinical evaluation to guide beta prototype (20 patients, single site).

Goal 2 (Y2Q1 – Y2Q4):
Prototype verification and clinical validation (40 patients, two sites).

Goal 3 (Y3Q1 – Y3Q4)
Development design transfer and complete FDA submission.

Product Development Research Priorities Addressed by the Recommended 19.1 Cycle Awards					
Funding novel projects that offer therapeutics or diagnostics not currently available, i.e., disruptive technologies	**Funding projects addressing large or challenging unmet medical needs**	**Investing in early stage projects when private capital is least available**	**Stimulating commercialization of technologies developed at Texas institutions**	**Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life sciences expertise, especially C-level staff to lead seed clusters of life science expertise at various Texas locations**	**Providing appropriate return on Texas taxpayer investment**
$30,770,917 **5 projects** • DP190027 • DP190025 • DP190020 • DP190021 • DP190018	**$30,770,917** **5 projects** • DP190027 • DP190025 • DP190020 • DP190021 • DP190018	**$30,770,917** **5 projects** • DP190027 • DP190025 • DP190020 • DP190021 • DP190018	**$11,742,509** **2 projects** • DP190020 • DP190021	**$22,028,408** **4 projects** • DP190027 • DP190025 • DP190020 • DP190018	**$30,770,917** **5 projects** • DP190027 • DP190025 • DP190020 • DP190021 • DP190018

Note: Some grant awards address more than one program priority and will be double counted.

January 23, 2019

Will Montgomery
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com
Via email to Will Montgomery's assistant, Laura Blevins, lblevins@jw.com

Wayne R. Roberts
Program Integration Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Will and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 19.1 grant award cycle.

The PDRC recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Hummingbird Bioscience, Allterum Therapeutics, Cell Medica, Icell Kealex Therapeutics and Instapath. The attached table reflects the ranked award recommendations, including the maximum recommended funding amounts and the overall evaluation scores for the five grant applications.

The PDRC did not make any changes to the goals, timelines, or budgets for the five projects recommended for funding. However, three of these recommendations are contingent on the review of the items described as follows:

- Execution of the CPRIT award contract for Allterum Therapeutics is contingent on the company's completion of the license agreement with the National Cancer Institute and CPRIT's review of documentation associated with the University of Maryland licensing agreement as outlined in the Vinson & Elkins IP Memorandum.
- Execution of the CPRIT award contract for Cell Medica is contingent on the company's completion of the recommendations set forth in the Vinson & Elkins IP Memorandum regarding patent coverage.
- Execution of the CPRIT award contract for Icell Kealex Therapeutics is contingent on resolution of the IP and licensing issues as outlined in the IP Diligence Memorandum from Baker Botts LLP.

The PDRC did not identify any contingencies associated with the awards to Hummingbird Bioscience or Instapath.

Each of companies included in the PDRC's recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PDRC's review of the due

diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

I will also note that the PDRC elected to take no action on two pending applications considered during due diligence review. Additional information is needed from the applicants before making final award decisions on DP190041 and DP190046. Once the applicants provide the requested information, the PDRC will reconvene and evaluate the data before making final award decisions. We anticipate that we will provide our award recommendations, if any, regarding these two pending proposals for consideration at either the May or August Oversight Committee meeting.

Sincerely,

/JG/ J Geltosky

Jack Geltosky, PhD

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations

FY 2019, Cycle 1

Rank	Application ID	Mech.	Company Name	Project	Maximum Recommended Budget	Overall Score
1	DP190027	RELCO	Hummingbird Bioscience Pte Ltd	A First-in-Class Anti-VISTA Monoclonal Antibody for the Treatment of MDSC-Mediated Suppression of Antitumor Immunity in Solid Tumors and Lymphomas	$13,116,095	2.0
2	DP190025	SEED	Allterum Therapeutics, LLC	Preclinical Development of a Novel T-ALL Therapeutic Antibody	$2,912,313	2.2
3	DP190020	SEED	Icell Kealex Therapeutics LLC	Development of a Novel Oncolytic Vaccinia Virus Variant Suitable for Systemic Delivery	$3,000,000	2.5
4	DP190021	TXCO	Cell Medica	Off-the-Shelf CAR-NKT Cells for Treatment of Solid and Hematological Malignancy	$8,742,509	3.1
5	DP190018	RELCO	Instapath Inc.	Rapid Pathology Evaluation System for Biopsies	$3,000,000	2.2
				Total	$30,770,917	

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

February 13, 2019

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of grant contracts for five companies that the Oversight Committee will consider for product development grant awards at its February 21, 2019, meeting. The Program Integration Committee has recommended these companies for grant awards.

Although CPRIT disburses most grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(a). Typically, the grant amount to be paid in advance is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, are required to submit quarterly financial status reports that are reviewed and approved by CPRIT's financial staff. The product development grant recipients must also certify that they have matching funds available to invest in the project prior to any disbursement of funds. Failure to submit the financial status reports on a timely basis or to certify matching funds will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

Advance payment of grant funds is necessary because the projects proposed for grant awards involve preclinical work and clinical trials. The cost structure for this type of work is highly front loaded and service providers require substantial upfront payments. Advancing grant funds allows these projects to begin work as quickly as possible.

Sincerely,

Wayne R. Roberts,
CPRIT Chief Executive Officer

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

SUBJECT: T.A.C. § 702.19 WAIVER

DATE: FEBRUARY 8, 2019

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I grant Kristen Doyle, CPRIT's Interim Chief Product Development Officer, a waiver from the general prohibition against communicating with grant applicants. The waiver is applicable to one product development applicant currently pending review by the Oversight Committee. No Oversight Committee action related to this waiver is necessary.

The Product Development Review Council and the Program Integration Committee (PIC) recommended a second product development award for Cell Medica, DP190021. The recommendation is currently pending Oversight Committee approval. CPRIT administrative rule § 702.19 prohibits substantive communication between the grant applicant and a member of the peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The restriction on communication is one way that CPRIT prevents even the appearance of unequal treatment during the grant review process.

Cell Medica received its first product development award from CPRIT in March 2012. Pursuant to CPRIT's revenue sharing agreement, the state owns equity in the company. Cell Medica has an active fundraising round that the company projects will end in March. If the Oversight Committee approves Cell Medica for a second award, it is possible that CPRIT may take additional equity in the company instead of sharing revenues through royalty payments. Good cause exists to allow Ms. Doyle to communicate with Cell Medica now to allow adequate time for CPRIT and Cell Medica to discuss CPRIT's participation in the current fundraising round. If discussions are delayed until after the February 21st Oversight Committee, there may be insufficient time to meaningfully and diligently discuss CPRIT's equity position.

Allowing Ms. Doyle to communicate with Cell Medica now does not indicate that the Oversight Committee will vote to approve an award for the company. This waiver will be part of the grant record for this application. The waiver will be publicly available once the Oversight Committee considers the application.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

February 8, 2018

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 54 grant applications totaling $95,956,032. The PIC recommendations for 42 academic research grant awards, 7 prevention awards, and 5 product development research awards are attached.

Dr. Jim Willson, CPRIT's Chief Scientific Officer, Dr. Becky Garcia, CPRIT's Chief Prevention Officer, and Ms. Kristen Doyle, CPRIT's Interim Chief Product Development Officer, have prepared overviews of the academic research, prevention, and product development research slates to assist your evaluation of the recommended awards. The overviews are intended to provide a comprehensive summary with enough detail to understand the substance of the proposal and the reasons endorsing grant funding. In addition to the full overviews, all of the information considered by the Review Councils is available by clicking on the appropriate link in the portal. This information includes the application, peer reviewer critiques, and the CEO affidavit for each proposal.

The PIC used the award deferral process set by CPRIT administrative rule § 703.7(d) to defer the decision to recommend awards for 10 academic research applications until a future FY 2019 meeting. All 10 of the deferred applications were recommended by the Scientific Review Council. The deferred applications include six Individual Investigator Research Awards, two Individual Investigator Awards for Cancers in Children and Adolescents, and two Individual Investigator Research Awards for Computational Biology. At the PIC meeting, Dr. Willson recommended deferring the awards due to program budget projections. For a list of the deferred applications, please refer to the separate deferral letter, located in the portal. No Oversight Committee action is necessary at this time.

The approval of these grant recommendations is governed by a statutory process that requires two-thirds of the members present and voting to approve each recommendation. Vince Burgess, CPRIT's Chief Compliance Officer, will certify that the review process for the recommended grants followed CPRIT's award process prior to any Oversight Committee action.

The award recommendations will not be considered final until the Oversight Committee meeting on February 21, 2019. Consistent with the non-disclosure agreement that all Oversight Committee members have signed, the recommendations should be kept confidential and not be disclosed to anyone until the award list is publicly announced at the Oversight Committee meeting. I request that Oversight Committee members not print, email or save to your computer's hard drive any material on the portal. I appreciate your assistance in taking all necessary precautions to protect this information.

If you have any questions or would like more information on the review process or any of the projects recommended for an award, CPRIT's staff, including myself, Dr. Willson, Dr. Garcia, and Ms. Doyle are always available. Please feel free to contact us directly should you have any questions. The programs that will be supported by the CPRIT awards are an important step in our efforts to mitigate the effects of cancer in Texas. Thank you for being part of this endeavor.

Sincerely,
Wayne R. Roberts
Chief Executive Officer

Academic Research Award Recommendations –

The PIC unanimously recommends approval of 42 academic research grant proposals totaling $52,856,653. The recommended grant proposals were submitted in response to seven grant mechanisms: Individual Investigator Research Awards; Individual Investigator Research Awards for Cancer in Children and Adolescents; Individual Investigator Research Awards for Computational Biology; Individual Investigator Research Awards for Prevention and Early Detection; Individual Investigator Research Awards for Clinical Translation; Recruitment of First-Time, Tenure-Track Faculty Members; and Recruitment of Rising Stars. The SRC provided the prioritized list of recommendations for the awards to the presiding officers on January 24, 2019. One application, RP190135, recommended by the SRC was withdrawn by the applicant prior to the PIC meeting; therefore, the PIC did not consider the application.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these academic research proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
- have a demonstrable economic development benefit to this state;
- enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources;
- expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and
- address the goals of the Texas Cancer Plan.

Academic Research Grant Award Recommendations

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
1	RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252
2	RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000
3	RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577
4	RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892
5	RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473
6	RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433
7	RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000
8	RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac	Noel, Cory V	Baylor College of Medicine	$1,192,412

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
				Dysfunction in Childhood Cancer Survivors			
9	RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000
10	RP190398	IIRA	**2.0**	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566
11	RP190019	IIRA	**2.0**	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000
12	RP190278	IIRA	**2.0**	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000
13	RP190192	IIRA	**2.1**	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000
14	RP190236	IIRA	**2.1**	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397
15	RP190279	IIRAP	**2.2**	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
				Carcinogenesis by Omega-3 Fatty Acids			
16	RP190160	IIRACT	**2.2**	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000
17	RP190107	IIRACB	**2.3**	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185
18	RP190256	IIRA	**2.4**	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992
19	RP190301	IIRA	**2.4**	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000
20	RP190077	IIRA	**2.4**	Molecular Action of Phospho-BRD4–Targeting Compounds in Breast Cancer	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	$864,000**
21	RP190435	IIRA	**2.4**	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000
22	RP190295	IIRA	**2.4**	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***
23	RP190326	IIRA	**2.4**	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000
24	RP190218	IIRA	**2.5**	Deciphering the Underlying Biology and Translational	Curran, Michael A	The University of Texas M. D.	$900,000

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
				Relevance of PD-L2		Anderson Cancer Center	
25	RP190252	IIRA	**2.5**	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000
26	RP190210	IIRAP	**2.5**	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527
27	RP190132	IIRACCA	**2.5**	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006
28	RP190385	IIRACCA	**2.6**	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000
29	RP190360	IIRACT	**2.6**	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991
30	RP190029	IIRA	**2.7**	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000
31	RP190131	IIRA	**2.7**	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907
32	RP190235	IIRA	**2.8**	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
				of Molecular Functions			
33	RP190002	IIRACCA	**2.8**	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218
34	RP190233	IIRACCA	**2.8**	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000
35	RP190454	IIRA	**2.9**	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000
36	RP190211	IIRA	**2.9**	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927

**RP190077 reflects budget as reduced by the SRC. SRC recommended the removal of the 3rd aim.
*** RP190295 SRC recommended requiring 10% effort for PI in order to fund.

IIRA: Individual Investigator Research Awards;
IIRACCA: Individual Investigator Research Awards for Cancer in Children and Adolescents;
IIRACB: Individual Investigator Research Awards for Computational Biology;
IIRAP: Individual Investigator Research Awards for Prevention and Early Detection;
IIRACT: Individual Investigator Research Awards for Clinical Translation

Academic Research Recruitment Grant Award Recommendations

Rank	App ID	Candidate	Mechanism	Organization	Budget	Overall Score
1	RR190023	Uri Ben-David, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	1.0
2	RR190025	Julian West, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	Rice University	$2,000,000	1.6
3	RR190020	Sangeetha Reddy, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.0
4	RR190027	Joshi Alumkal, M.D.	Recruitment of Rising Stars	The University of Texas Southwestern Medical Center	$4,000,000	2.0
5	RR190029	Ravikanth Maddipati, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.2
6	RR190021	Di Zhao, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	2.8

Prevention Award Recommendations –

The PIC unanimously recommends approval of seven prevention grant proposals totaling $12,328,462. The recommended grant proposals were submitted in response to the following mechanisms: Tobacco Control and Lung Cancer Screening; Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations; and Dissemination of CPRIT-Funded Cancer Control Interventions. The Prevention Review Council (PRC) provided its recommendation to the presiding officers on January 14, 2019. The PIC approved the recommended rank order as presented by the PRC.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these product development proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
- have a demonstrable economic development benefit to this state; and
- address the goals of the Texas Cancer Plan.

Prevention Grant Award Recommendations

Rank	App. ID	Mech.	Application Title	PD	Organization	Rec Budget	Average Overall Score
1	PP190009	TCL	Expanding Tobacco Use Cessation in Northeast Texas	Prokhorov, Alexander V	The University of Texas M. D. Anderson Cancer Center	$1,499,956	2.1
2	PP190027	TCL	Engaging Oral Health Providers for Evidence-Based Tobacco Cessation	Jones, Daniel L	Texas A&M University System Health Science Center	$1,499,871	2.7
3	PP190004	EPS	Partnering with schools and clinics to expand a highly successful HPV vaccination program for 9-17 year olds from Medically Underserved Areas	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$2,499,411	1.5
4	PP190021	EPS	Access to Breast and Cervical Care for west Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	$2,430,998	1.6
5	PP190023	EPS	School-based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuation and Expansion to Hidalgo County	Rodriguez, Ana M	The University of Texas Medical Branch at Galveston	$1,969,731	1.9
6	PP190014	EPS	Expansion of cervical cancer prevention services to medically underserved populations through patient outreach, navigation & provider training/telementoring	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	$2,128,529	2.6
7	PP190041	DI	Adolescent Vaccination Program: Online Decision Support for Adoption of Evidence-based HPV Vaccination Strategies by Texas Pediatric Clinics	Shegog, Ross	The University of Texas Health Science Center at Houston	$299,966	2.0

EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
TCL: Tobacco Control and Lung Cancer Screening
DI: Dissemination of CPRIT-Funded Cancer Control Interventions

Product Development Research Award Recommendations –

The PIC unanimously recommends approval of five product development research grant proposals totaling $30,770,917. The recommended grant proposals were submitted in response to the following mechanisms: Texas Company Product Development Awards, Company Relocation Product Development Research Awards, and Seed Awards for Product Development Research. The Product Development Review Council (PDRC) provided its recommendation to the presiding officers on January 23, 2019. The PIC approved the recommended rank order as presented by the PDRC.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these product development proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- are interdisciplinary or interinstitutional;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
    - Texas Company Product Development Awards only
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
    - Seed Awards for Product Development Research, Texas Company Product Development Awards only
- have a demonstrable economic development benefit to this state;
- expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and
- address the goals of the Texas Cancer Plan.
    - Texas Company Product Development Awards only

Product Development Grant Award Recommendations

Rank	Application ID	Mech.	Company Name	Project	Recommended Budget	Overall Score
1	DP190027	RELCO	Hummingbird Bioscience Pte Ltd	A first-in-class anti-VISTA monoclonal antibody for the treatment of MDSC-mediated suppression of anti-tumor immunity in solid tumors and lymphomas	$13,116,095	2.0
2	DP190025	SEED	Allterum Therapeutics, LLC	Preclinical Development of a Novel T-ALL Therapeutic Antibody	$2,912,313	2.2
3	DP190020	SEED	Icell Kealex Therapeutics, LLC	Development of a Novel Oncolytic Vaccinia Virus Variant Suitable for Systemic Delivery	$3,000,000	2.5
4	DP190021	TXCO	Cell Medica	Off the Shelf CAR-NKT Cells for Treatment of Solid and Hematological Malignancy	$8,742,509	3.1
5	DP190018	SEED	Instapath, Inc.	Rapid pathology evaluation system for biopsies	$3,000,000	2.2

TXCO: Texas Company Product Development Awards
RELCO: Company Relocation Product Development Research Awards
SEED: Seed Awards for Product Development Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

February 8, 2019

Dear Oversight Committee Members:

Pursuant to Texas Administrative Code § 703.7(d), the Program Integration Committee (PIC) unanimously voted to defer the following 10 Academic Research applications that were recommended by the Scientific Review Council (SRC):

RP190251
RP190414
RP190287
RP190421
RP190346
RP190366
RP190208
RP190401
RP190358
RP190259

The deferred applications include six Individual Investigator Research Awards, two Individual Investigator Awards for Cancers in Children and Adolescents, and two Individual Investigator Research Awards for Computational Biology.

While all are meritorious projects and received favorable scores, the PIC deferred these applications due to CPRIT overall budget concerns throughout FY2019. The PIC may consider and recommend the deferred applications at a later date in the fiscal year.

Deferring these 10 applications now allows CPRIT more flexibility when considering any award recommendations for the remainder of the fiscal year. No Oversight Committee action is necessary at this time.

Sincerely,

Wayne R. Roberts
Chief Executive Officer

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE CERTIFICATION – FEBRUARY 2019 AWARDS
DATE:	FEBRUARY 7, 2019

Summary and Recommendation:

As CPRIT's Chief Compliance Officer, I am responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process. I have reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the:

- Recruitment of Rising Stars
- Recruitment of First-Time, Tenure-Track Faculty Members
- Individual Investigator Research Awards
- Individual Investigator Research Awards for Childhood and Adolescent Cancer
- Individual Investigator Research Awards for Computational Biology
- Individual Investigator Research Awards for Clinical Translation
- Individual Investigator Research Awards for Prevention and Early Detection
- Texas Company Product Development Research Awards
- Company Relocation Product Development Research Awards
- Seed Awards for Product Development Research
- Tobacco Control and Lung Cancer Screening
- Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
- Dissemination of CPRIT-Funded Cancer Control Interventions

I have conferred with staff at CPRIT and General Dynamics Information Technology (GDIT), CPRIT's contracted third-party grants administrator, regarding the academic research, product development research, and prevention awards and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the above mechanisms recommended by the Program Integration Committee (PIC) followed applicable laws and agency administrative rules. I certify the academic

research, product development research, and prevention award recommendations for the Oversight Committee's consideration. I note that the following mechanisms received applications; however, none were recommended by the Review Councils or considered by the PIC: Recruitment of Established Investigators and Evidence-Based Cancer Prevention Services.

Background:

CPRIT's Chief Compliance Officer must report to the Oversight Committee regarding compliance with the statute and the agency's administrative rules. Among the Chief Compliance Officer's responsibilities is the obligation "to ensure that all grant proposals comply with this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval." Texas Health & Safety Code § 102.051(c) and (d).

CPRIT uses a compliance pedigree process to formally document compliance for the grant award process. The compliance pedigree tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. A compliance pedigree is created for each application; the information related to the procedural steps listed on the pedigree is entered and attested to by GDIT employees and CPRIT employees. CPRIT relies on GDIT to accurately record a majority of the information on the pedigree from the pre-receipt stage to final Review Council recommendation. To the greatest extent possible, information reported in the compliance pedigree is imported directly from data contained in CPRIT's Application Receipt System (CARS), the grant application database managed by GDIT. This is done to minimize the opportunity for error caused by manual data entry.

No Prohibited Donations:

Although CPRIT is statutorily authorized to accept gifts and grants pursuant to Texas Health & Safety Code § 102.054, the statute prohibits CPRIT from awarding a grant to an applicant who has made a gift or grant to CPRIT or a nonprofit organization established to provide support to CPRIT. I note that Texas Health & Safety Code § 102.251(a)(3) specifically addresses "donors from any nonprofit organization established to provide support to the institute compiled from information made available under § 102.262(c)." To the best of my knowledge, there are no nonprofit organizations that have been established to provide support to CPRIT on or after June 14, 2013, the effective date of this statutory change. The only nonprofit organization established to provide support to the Institute was the CPRIT Foundation; however, the CPRIT Foundation ceased operations and changed its name and its purpose prior to June 14, 2013. The institute has received no donations from the CPRIT Foundation made on or after June 14, 2013**.**

I have reviewed the list of donors to CPRIT maintained by CPRIT (and listed on CPRIT's website) and compared the donors to the list of applicants. No donors to CPRIT have submitted applications for grant awards during the award cycles that are the subject of this report.

Pre-Receipt Compliance:

The activities listed on a compliance pedigree in the pre-receipt stage cover the period beginning with CPRIT's approval and issuance of the Request for Applications (RFA) through the submission of grant applications. For the period covering these RFAs, CPRIT published the RFAs on the Texas.gov eGrants website. The RFA specifies a deadline and mandates that only those applications submitted electronically through CPRIT's Application Receipt System (CARS) are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to CPRIT (through the CPRIT Helpdesk that is managed by GDIT) to allow for a submission after the deadline. The program officer considers any requests for extension and may approve an extension for good cause. When a late filing request is approved, the applicant is notified and CARS is reopened for a brief period – usually two to three hours – the next business day.

Academic Research:

For Recruitment Cycles 19.4-5 and 19.6, one application was received for the Recruitment of Established Investigators RFA, one application was received in response to the Recruitment of Rising Stars RFA, and seven applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA.

In response to the academic, non-recruitment RFAs for Cycle 19.1, CPRIT received 401 applications. Twelve applications were administratively withdrawn prior to Peer Review. For the non-recruitment mechanisms, a preliminary evaluation process was utilized as allowed by T.A.C.§ 703.6(e)(1). Based on the scores of the preliminary evaluation, 160 academic, non-recruitment applications did not move forward to the full review phase. The remaining 229 academic research, non-recruitment applications moved forward to full review. It should be noted that two academic research, non-recruitment applications were voluntarily withdrawn by the applicant after the full review phase. One application was withdrawn before the SRC and one application was withdrawn after the SRC.

All academic research RFAs were posted on the Texas.gov eGrants website and all applications were submitted through CARS. Two applicants requested an extension to submit an application after the deadline. The program officer determined that there was good cause for the requests and the deadline was extended.

Product Development Research:

For Cycle 19.1, five applications were received for the Texas Company Product Development Awards RFA, nine applications were received for the Company Relocation Product Development Research Awards RFA, and 27 applications were received for the Seed Awards for Product Development Research RFA. Three applications were administratively withdrawn prior to peer review.

All product development research RFAs were posted on the Texas.gov eGrants website and all applications were submitted through CARS. Seven applicants requested an extension to submit an application after the deadline. The program officer determined that there was good cause for five of the requests and the deadline was extended for those five applicants.

Prevention:

For Cycle 19.1, nine applications were received for the Evidence-Based Cancer Prevention Services RFA, four applications were received for the Tobacco Control and Lung Cancer Screening RFA, seven applications were received for the Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations RFA, and two applications were received for the Dissemination of CPRIT-Funded Cancer Control Interventions RFA. Two applications were administratively withdrawn prior to peer review.

All prevention RFAs were posted on the Texas.gov eGrants website and all applications were submitted through CARS. One applicant requested an extension to submit an application after the deadline. The program officer determined that there was good cause for the request and the deadline was extended.

Receipt, Referral, and Assignment Compliance:

Once applications have been submitted through CARS, GDIT staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, GDIT notifies the program officer and the program officer makes the final decision whether to administratively withdraw the application. Recruitment grant applications are assigned to the Scientific Review Council members for peer review. All other academic research, product development research, and prevention applications are assigned by the peer review panel chair to their respective peer review panels. Prior to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

The pedigrees attest that a conflict of interest statement was signed by each primary reviewer for each Grant Application.

Academic Research:

As stated earlier, twelve academic research, non-recruitment applications were administratively withdrawn prior to peer review. In addition, two academic research, non-recruitment applications were voluntarily withdrawn by the applicant after the full review phase. Of these two applications, one was withdrawn before the SRC and one was withdrawn after the SRC, but prior to the Program Integration Committee (PIC) meeting.

Product Development Research:

Three applications were administratively withdrawn prior to peer review.

Prevention:

Two applications were administratively withdrawn prior to peer review.

Peer Review:

Primary reviewers (typically three) must submit written critiques for each of their assigned applications prior to the peer review meeting. Sign out sheets are used to document when a reviewer with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application.

Following the peer review meeting, each participating peer reviewer must sign a post-review peer review statement certifying that the reviewer knew of and understood CPRIT's conflict of interest policy and followed the policy for this review process. After the peer review meetings, a final score report from the review committee is delivered to the Review Council for additional review.

Academic Research:

For the Recruitment Awards, the applications are reviewed by the Scientific Review Council (SRC), which assigns two members of the SRC to be primary reviewers. I reviewed the supporting documentation, such as the sign-out sheets, third-party observer reports, and post-review peer reviewer statements. Sign out sheets are used to document when a reviewer with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application. For Cycles 19.4-5 and 19.6, no conflicts of interest were declared by the SRC.

I reviewed and confirmed that the post review conflict of interest statements were signed by the six SRC members that attended the Recruitment Review Panel meeting on December 13, 2018 and the six SRC members that attended the Recruitment Review Panel meeting on January 17, 2019.

Academic research applications (non-recruitment) are reviewed by peer review panels and recommended to the Scientific Review Council. As documented by GDIT, reviewers with conflicts of interest did not participate in review of those applications. I reviewed supporting documentation,

such as conflict of interest statements (COIs), third-party observer reports, and sign out sheets. All declared COIs left the room or disengaged from the conference call and did not participate in the discussion of relevant applications.

I also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members for each review panel as well as the seven SRC members that attended the Review Council meeting on December 5, 2018.

Product Development Research:

Product Development Research awards go through a peer review teleconference screening call to determine which applications will be invited to in-person review. Those applicants that attend in-person review are once again evaluated by peer reviewers. Applicants recommended after in-person review must then go through operations and management due diligence review, which is conducted by outside contractors and outside intellectual property counsel. The Product Development Review Council (PDRC) recommends awards after due diligence to the PIC. I have verified from GDIT documentation and the third-party observer reports that those reviewers with conflicts did not participate in review of applications for which they indicated a conflict of interest. All declared COIs left the room or disengaged from the conference call and did not participate in the discussion of relevant applications.

I also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members for each panel as well as the five PDRC members and five expert reviewers that attended the Due Diligence meeting on January 11, 2018, the five PDRC members and three expert reviewers that attended the Due Diligence meeting on January 14, 2019, and the six PDRC members that attended the Ranking of Due Diligence Applications meeting on January 22, 2019.

It should be noted that within the Texas Company Product Development Research Award mechanism, one application was recommended ahead of two applications with either the same or more favorable score. Additionally, in the PDRC recommendation letter sent to the PIC, three applications recommended by the PDRC were ranked ahead of an application with either an equal to or more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

Prevention:

For the Dissemination of CPRIT-Funded Cancer Control Interventions RFA, the applications are reviewed by the Prevention Review Council (PRC), which assigns two members of the PRC to be primary reviewers. All other Prevention applications are reviewed by peer review panels and then sent to the Prevention Review Council (PRC).

I reviewed the supporting documentation, such as the sign-out sheets, third-party observer reports, and post-review peer reviewer statements. As documented by GDIT and verified by third-party observer reports, reviewers with conflicts of interest did not participate in review of those applications. All declared COIs left the room or disengaged from the conference call and did not participate in the discussion of relevant applications.

I reviewed and confirmed that the post review conflict of interest statements were signed by peer review members for Prevention Panel 1 on December 11-12, 2018 and the Dissemination of CPRIT-Funded Cancer Control Interventions Panel on January 11, 2019, as well as the three PRC members that attended the PRC meeting on January 11, 2019.

Programmatic Review:

Programmatic review is conducted by the Scientific Review Council, Prevention Review Council, and Product Development Review Council for their respective awards. Each review council creates a final list of grant applications it will recommend to the PIC for grant award slates.

To the extent that any Review Council member identified a conflict of interest, I reviewed documentation confirming that the review council member did not participate in the discussion or vote on the application(s).

I also reviewed the third-party observer reports for each Review Council meeting. The third-party observer reports document that the Review Council discussions were limited to the merits of the applications and established evaluation criteria and that conflicted reviewers, if applicable, exited the room or the conference call when the application was discussed.

For the Academic Research and Prevention awards, I reviewed and confirmed that the Review Council recommendations corresponded to RFAs that had been released. I also confirmed that the pedigrees reflect the date of the Review Council meeting and that the applications were recommended by the Review Council.

<u>Academic Research</u>:

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. Each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1 for example, another panel may

decide based on the totality of factors that an application with a score greater than 3.1 should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The SRC met on December 5, 2018 to consider 47 applications recommended by the peer review panels following their meetings held on October 18 – October 25, 2018. After review and discussion of these applications, the SRC recommended all 47 applications to the Program Integration Committee (PIC) for consideration.

Product Development Research:

For Cycle 19.1, nine applications went through due diligence. An additional application from Cycle 18.2 was included in the discussion having already gone through due diligence in that cycle. I noted in my August 2018 compliance certification that the PDRC was seeking additional information from this grantee following the due diligence review.

The Product Development Review Council (PDRC) recommended five applications to the Program Integration Committee (PIC). I note that pursuant to § 702.19(e), Wayne Roberts, Chief Executive Officer, granted the Interim Chief Product Development Officer (CPDO) a waiver from the general prohibition on communication upon a finding that the waiver was in the best interest of the Institute and was not intended to give one applicant advantage over another. The Oversight Committee was notified of the waiver on February 8, 2019, in writing. The waiver allows the Interim CPDO to discuss equity issues with one of the companies.

The PDRC is seeking additional information from two applicants from cycle 19.1 following due diligence review. Once applicants provide the requested information, the PDRC will reconvene and issue final award decisions. It is anticipated that the Oversight Committee will consider the PDRC award recommendations, if any, regarding these two applications at an Oversite Committee meeting later in FY19.

CPRIT's newly hired Chief Product Development Officer, Cindy WalkerPeach, listened in on the January 11 and January 14 meetings. Prior to due diligence, she completed the necessary paperwork to certify that she had no conflict of interest, as defined by CPRIT's statute and rules, with the applications that were discussed during due diligence review.

Prevention:

It should be noted that during the peer review panel discussion of a prevention application, Dr. Ross Brownson, a PRC member, declared a conflict of interest and recused himself. When the PRC ranked this application at their review council meeting, Dr. Brownson inadvertently failed to initially disclose the conflict of interest and participated in the discussion, but not the ranking, of the application. Dr. Brownson's participation is addressed by the FY2019 conflict of interest waiver

adopted by the Oversight Committee in August 2018 that allows review council members with certain conflicts of interest to participate in discussion of applications that reach the review council stage of application review. The conflict of interest by the PRC member falls within the allowable limits of this waiver and did not interfere with the integrity of the review process.

Some applications with more favorable or equivalent scores to applications that were recommended for awards did not move forward to the PIC. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

Program Integration Committee (PIC) Review:

Texas Health & Safety Code § 102.051(d) requires the Chief Compliance Officer to attend and observe the PIC meetings to ensure compliance with CPRIT's statute and administrative rules. CPRIT's statute requires that, at the time the PIC's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the PIC containing relevant information related to the Grant Application recommendations.

I attended the February 7, 2019, PIC meeting as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules. The PIC considered 64 applications that were recommended by the three review councils. The Chief Scientific Officer recommended that action be deferred until a later meeting in FY19 on 10 academic research non-recruitment awards. The PIC unanimously voted to defer those 10 award recommendations; therefore, 54 applications were recommended to move forward to the Oversight Committee. A review of the CEO affidavits confirms that such affidavits were executed and provided for each Grant Application recommendation.

Compliance Templates

- Grant Application Pedigree
- Conflict of Interest Sign-out Sheet
- Post Review Statement
- Third Party Observer Report

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY
CYCLE
PROGRAM Academic Research
AWARD MECHANISM
APPLICATION ID RPxxxxxx

APPLICATION TITLE

APPLICANT NAME
ORGANIZATION
PANEL NAME

Category	Compliance Requirement	Information	Attestation Date	Attesting Party
1. Pre-Receipt	RFA approved by CSO	DATE		
	RFA published in Texas.gov eGrants	DATE		
	CPRIT Application Receipt System (CARS) opened	DATE		
	CPRIT Application Receipt System (CARS) closed	DATE		
	Date application submitted	DATE		
	Method of submission	CARS		
	Within receipt period	YES/NO		
	Request for extension to submit application after CARS closed	DATE or N/A		
	Request for extension for late application submission accepted	YES/NO or N/A		
2. Receipt, Referral, and Assignment	Administrative review notification	DATE or N/A		
	Donation(s) made to CPRIT/foundation	YES/NO		
	Assigned to primary reviewers	DATE		
	Applicant notified of review panel assignment	DATE		
	Primary Reviewer 1 COI signed	DATE		
	Primary Reviewer 2 COI signed	DATE		
	Primary Reviewer 3 COI signed	DATE		
	Primary (Advocate) Reviewer 4 COI signed	DATE		
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	DATE		
	Primary Reviewer 2 critique submitted	DATE		
	Primary Reviewer 3 critique submitted	DATE		
	Primary (Advocate) Reviewer 4 critique submitted	DATE		
	COI indicated by non-primary reviewer	NAME or NONE		
	Preliminary Evaluation score summary sent to Chair	DATE		
	Recommended for full review	YES/NO		
	Applicant notified of outcome	DATE		
4. Peer Review Meeting	Assigned to primary reviewers	DATE		
	Primary Reviewer 1 COI signed	DATE		
	Primary Reviewer 2 COI signed	DATE		
	Primary Reviewer 3 COI signed	DATE		
	Primary (Advocate) Reviewer 4 COI signed	DATE		
	Primary Reviewer 1 critique submitted	DATE		
	Primary Reviewer 2 critique submitted	DATE		
	Primary Reviewer 3 critique submitted	DATE		
	Primary (Advocate) Reviewer 4 critique submitted	DATE		
	COI indicated by non-primary reviewer	NAME or NONE		
	COI recused from participation	YES/NO or N/A		
	Discussed at Peer Review Meeting	YES/NO or N/A		
	Peer Review Meeting	DATE		
	Post review statements signed	DATE		
	Third Party Observer Report	DATE		
	Score report delivered to CSO	DATE		
	Recommended for SRC Review	YES/NO		
5. Final SRC Recommendation	COI indicated by SRC member	NAME or NONE		
	COI recused from participation	YES/NO or N/A		
	SRC Meeting	DATE		
	Third Party Observer Report	DATE		
	Recommended for grant award	YES/NO		
	SRC Chair Notification to PIC and OC	DATE		
6. PIC Review	COI indicated by PIC member	NAME or NONE		
	COI recused from participation	YES/NO or N/A		
	PIC review meeting	DATE		
	Recommended for grant award	YES/NO		
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE		
	COI indicated by Oversight Committee member	NAME or NONE		
	COI recused from participation	YES/NO or N/A		
	Donation(s) made to CPRIT/foundation	YES/NO		
	Presented to CPRIT Oversight Committee	DATE		
	Award approved by Oversight Committee	YES/NO		
	Authority to advance funds requested	YES/NO		
	Advance authority approved by Oversight Committee	YES/NO		

Peer Review Certification of Non-Participant in
Evaluation of Individual Applications Because of Real or Apparent Conflict of Interest
Panel: Recruitment FY19 Cycle 7
Meeting: Teleconference

This is to certify that I was not present and did not participate in the review of the following applications:

Date	Application Number	Applicant/PD/PI Name	Applicant/PD/PI Organization	Reviewer Name	Reviewer Signature	GDIT Name/ Initials*

GDIT Approval:

Name (PRINT): _____

Signature: _____

Date: _____

Comments:

*A GDIT representative will add their name and initials to the form to acknowledge that the reviewer identified as a Conflict of Interest has signed the form and left the panel room during the discussion of the application

Panel Dates

POST REVIEW STATEMENT FOR CPRIT SCIENTIFIC RESEARCH AND PREVENTION PROGRAM (SRPP) COMMITTEE MEMBERS

I understand the conflict of interest policies of CPRIT and have reported any conflicts of interest that I may have with respect to applications submitted to my assigned SRPP committee for review. By my signature, I affirm that I did not participate in the discussion or review of any application that presents a conflict of interest as defined by the CPRIT Conflict of Interest Policy for SRPP Committee Members.

Signature: _____ Date: _____

Printed Name: _____

Cancer Prevention and Research Institute of Texas (CPRIT)
Example Peer Review Meeting (XX.II EPR)
Observation Report

Report No.	Year –MO-DY XX.II EPR
Program Name:	Academic Research
Panel Name:	Example Peer Review Meeting (XX.II_EPR)
Panel Date:	7/12/2018
Report Date:	7/12/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the _____ meeting. The meeting was chaired by _____ and conducted via _____ (in-person or teleconference) on _____ (date).

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. CSRA, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: ____ (x) applications were discussed and considered
- Panelists: ___ (x) panel chair and __ (x) expert reviewers and ____ (x) advocate reviewers
- ICON employees: _____ (x)
- Panelists' discussions were limited to the application evaluation criteria
- CSRA staff employees: _____(x)
- CSRA staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: _____(x)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were ____ (x) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were (not) provided by CSRA to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was (not) provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Dissemination of CPRIT-Funded Cancer Control Interventions

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA P-19.1-DI

Dissemination of CPRIT-Funded Cancer Control Interventions

Please also refer to the Instructions for Applicants document, which will be posted on June 7, 2018

Application Receipt Dates: June 7, 2018-June 4, 2019

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

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RFA VERSION HISTORY

Rev 05/10/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and enhance the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary, and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize underserved populations

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

The **Dissemination of CPRIT-Funded Cancer Control Interventions (DI)** award mechanism seeks to fund programs that facilitate the continuation of CPRIT projects through their dissemination and implementation across Texas. **This award mechanism is open only to previously or currently funded CPRIT projects.** Applicants may request any amount of funding up to a maximum of $300,000 in total funding over a maximum of 24 months.

The proposed program should describe and package strategies or approaches to introduce, modify, and implement previously funded CPRIT evidence-based cancer prevention and control interventions for dissemination to other settings and populations in the state. To be eligible, the applicant should be in a position to develop 1 or more "products" based on the results of the CPRIT-funded intervention. Of particular interest is the dissemination of "products" that address the unique challenges to program implementation in resource-limited settings, particularly in nonmetropolitan and medically underserved areas of the state.

The proposed projects should also identify and assist others in preparing to implement the intervention and/or preparing to apply for grant funding.

2.2. Project Objectives

CPRIT seeks to fund projects that will provide 1 or more of the following:

- Dissemination of tools or models to public health professionals, health care practitioners, health planners, policymakers, and advocacy groups;
- Dissemination of materials or information about an intervention to broader settings/systems; and
- Dissemination or scaling up of best practices (infrastructure and tools) and evidence-based interventions for implementation (ie, implementation guides).

2.3. Award Description

The **Dissemination of CPRIT-Funded Cancer Control Interventions** RFA solicits applications from currently or previously funded CPRIT projects that have demonstrated exemplary success and have materials, policies, and other resources that have been successfully implemented and evaluated and could be scaled up and/or applied to other systems and settings. The ultimate goal is to continue and expand successful models for the delivery of prevention interventions all across the state through adaptation or replication.

The Center for Research in Implementation Science and Prevention website (http://www.dissemination-implementation.org/measures.aspx) defines active and passive dissemination strategies as follows: "Dissemination strategies describe mechanisms and approaches that are used to communicate and spread information about interventions to targeted users. Dissemination strategies are concerned with the packaging of the information about the intervention and the communication channels that are used to reach potential adopters and target audience. Passive dissemination strategies include mass mailings, publication of information including practice guidelines, and untargeted presentations to heterogeneous groups. Active dissemination strategies include hands on technical assistance, replication guides, point-of-decision prompts for use, and mass media campaigns. It is consistently stated in the literature that dissemination strategies are necessary but not sufficient to ensure wide-spread use of an intervention."

Adopters will need to employ implementation strategies to replicate or adapt projects to their settings or populations. Implementation strategies are described as the systematic processes, activities, and resources that are used to integrate interventions into usual settings. Core implementation components or implementation drivers can be staff selection, preservice and in-service training, ongoing consultation and coaching, staff and program evaluation, facilitative administrative support, and systems interventions. (See http://www.dissemination-implementation.org/measures.aspx)

This award will support both passive and active dissemination strategies but must include 2 or more active dissemination strategies. This award will also support implementation strategies in the form of technical assistance, coaching, and consultation within the time period of the grant. CPRIT recognizes that there are limits to the amount of technical assistance or coaching that can be accomplished within the grant period; however, priority will be given to those projects that

identify and assist potential adopters in preparing to implement the intervention and/or preparing to apply for grant funding. Examples of active dissemination strategies and implementation strategies follow.

Tools/models

- Toolkits with materials, sample policies, and procedures for implementation of CPRIT-funded programs
- Interactive websites that provide future adopters with key information on how to implement CPRIT-related interventions
- Approaches for dissemination of findings via nontraditional channels (eg, social media)
- User-friendly summaries—short issue or policy briefs that tell a story for decision makers based on CPRIT findings
- Brief, user-friendly case studies from program developers and recipients to illustrate key issues

Implementation guides

- Targeted communication materials emphasizing how to apply them to different populations, systems, and settings
- Step-by-step implementation guides on how to translate an evidence-based intervention/program to broader settings, including guidelines for retaining core elements of the interventions or programs while offering suggested adaptations for the elements that would enhance the adoption and sustainability of the programs in different populations, settings, or circumstances (See Partnership for Prevention examples: https://innovations.ahrq.gov/qualitytools/community-health-promotion-handbook-action-guides-improve-community-health)

Training/Technical assistance

- Provision of training and technical assistance to guide adopters in developing their plans to adapt, refine, and implement their projects

In addition, proposed dissemination materials should include a discussion of barriers to dissemination; a description of personnel and necessary resources to overcome barriers to implementation of the project; a description of expected outcomes, evaluation strategies with a

sample evaluation plan, and tools (if applicable); and suggestions or plan for project sustainability.

By the end of Year 1, the project timeline should include but is not limited to the following:

- A step-by-step implementation guide that includes how to translate an evidence-based intervention/program to broader settings, including guidelines for retaining core elements of the interventions or programs while offering suggested adaptations for the elements that would enhance the adoption and sustainability of the programs in different populations, settings, or circumstances.

Under this RFA, CPRIT **will not** consider the following:

- **Applications to disseminate projects not previously or currently funded by CPRIT**
- **Projects involving prevention/intervention research**.

Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).

2.4. Priorities

Types of Cancer:

Applications addressing any cancer type(s) that are responsive to this RFA will be considered for funding. See section 2.5 for specific areas of emphasis. Priority will be given to applications to disseminate and replicate projects that when implemented can address the following program priorities set by the CPRIT Oversight Committee:

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence;
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence;
- Prioritize underserved populations.

Priority Populations

The age of the priority population described in the application must comply with established and current national guidelines (eg, US Preventive Services Task Force [USPSTF], American Cancer Society, American College of Physicians).

Priority populations are subgroups that are underserved and disproportionately affected by cancer. Insured populations are not the priority of CPRIT's programs; however, some health promotion and education activities may include insured individuals as well as those who are underinsured or uninsured.

CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals;
- Geographically or culturally isolated populations;
- Medically unserved or underserved populations;
- Populations with low health literacy skills;
- Racial, ethnic, and cultural minority populations; or
- Other populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance with nationally recommended screening guidelines.

2.5. Specific Areas of Emphasis

Applications that propose dissemination of any previously funded CPRIT project delivering an evidence-based preventive service or education and outreach program that includes navigation to services that is responsive to this RFA will be considered. However, CPRIT has identified the following area of emphasis for this cycle of awards.

- Dissemination of the programs that address the unique challenges to program implementation in resource-limited settings, in particular, nonmetropolitan and medically underserved areas of the state.

2.6. Outcome Metrics

The applicant is required to describe how the goals and objectives for each year of the project as well as the final outcomes will be measured. The applicant should provide a clear and appropriate plan for data collection and interpretation of results to report against goals and objectives.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to the following:
  - Narrative on project progress, including the number and description of all active and passive dissemination and implementation activities undertaken.
- Annual and final progress report sections include, but are not limited to the following:
  - Key accomplishments, including discussion of barriers to dissemination,
  - Progress toward goals and objectives,
  - Materials produced, presentations, publications, etc,
  - Economic impact of the project.

2.7. Eligibility

- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The applicant may submit more than 1 application, but each application must be for distinctly different projects without overlap in the projects. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key

personnel listed on the grant application, or any officer or director of the grant applicant's organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.

- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 6. All statutory provisions and relevant administrative rules can be found at http://www.cprit.texas.gov.

2.8. Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 4 or higher are likely to need considerable attention. All resubmitted applications should be carefully

reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

2.9. Funding Information

Applicants may request any amount of funding up to a maximum of $300,000 in total funding over a maximum of 24 months. Grant funds may be used to pay for salary and benefits, project supplies, equipment, costs for outreach and education, and travel of project personnel to project site(s). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the **total** award amount.

The budget should be well justified. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

3. KEY DATES

Applications will be accepted on a continuous basis throughout FY 2019; application review and award notification will generally occur twice per year according to the schedule below. For an application to be considered for review during a given review cycle, that application must be submitted on or before 11:59 PM central time on the respective deadline date.

FY 2019	Application Deadline	Application Review	Oversight Committee Award Approval
19.1	12/3/2018	January 2019	February 2019
19.2	6/4/2019	July 2019	August 2019

4. APPLICATION SUBMISSION GUIDELINES

4.1. *Instructions for Applicants* document

It is imperative that applicants read the accompanying instructions document for this RFA that will be available June 7, 2018 (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on June 7, 2018, and will be accepted on a continuous basis throughout FY 2019. Applications will generally be reviewed twice per year. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details. **Submissions that are missing 1 or more components or do not meet the eligibility requirements may be administratively withdrawn without review.**

4.4.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need for the proposed project.
- **Overall Project Strategy:** Describe the project and how it will address the identified need.
- **Specific Goals:** State specifically the overall goals of the proposed project.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control and for the State of Texas.

4.4.2. Goals and Objectives (700 characters each)

List only major **outcome** goals and **measurable** objectives for each year of the project. **Do not include** process objectives; these should be described in the project plan only. Include the measure within the stated objective. The maximum number is 3 outcome goals with 3 objectives each. Projects will be evaluated annually on progress toward **outcome** goals and objectives. See Appendix for instructions on writing **outcome** goals and objectives.

A baseline and method(s) of measurement are required for each objective. If a baseline has not yet been defined, applicants are required to explain plans to establish baseline and describe method(s) of measurement.

4.4.3. Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1 and 2, and Months 1, 2, 3, etc, as applicable instead of specific months or years (eg, Year 1, Months 3-5). Month 1 is the first full month of the grant award.

4.4.4. Project Plan (12 pages; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below.

Background: Describe the project to be disseminated and how and why it lends itself to replication and scalability. Describe the effectiveness of the intervention that is being proposed for replication/dissemination and the expected short- and long-term impacts of the project.

Goals and Objectives: Process objectives should be included in the project plan. Outcome goals and objectives will be entered in separate fields in CARS. However, if desired, outcome goals and objectives may be fully repeated or briefly summarized here. See Appendix for instructions on writing goals and objectives.

Components of the Project: Clearly describe the data demonstrating success of the CPRIT-funded project that justifies dissemination. Describe components of the proposed dissemination project and the dissemination approach, strategy (eg, passive and active dissemination and implementation strategies), and the products being designed or packaged. The dissemination approach and strategy should also consider the message, source, audience, and channel (Brownson, R.C., et al. *J Pub Health Manag Pract*. 24(2):102-111, March/April 2018). Clearly describe the established theory and practice that support the proposed approach or strategy. Describe parameters of the CPRIT-funded project that may affect its dissemination and replication, such as target audience for which it was designed, specialized resources that may be needed, or geographic considerations.

Evaluation Strategy: Describe the evaluation plan and methodology to assess dissemination effectiveness (eg, include short-term and intermediate impact of dissemination activities, knowledge and behavior change among the audience likely to adopt the project). Describe a clear and appropriate plan for data collection and interpretation of results to report against goals and objectives. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, or the

like. Applicants should budget accordingly for the evaluation activity and should ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its qualifications and capabilities to deliver the proposed project. Describe the role and qualifications of key collaborating organizations/partners (if applicable) and how they add value to the project and demonstrate commitment to working together to implement the project. Describe the key personnel who are in place or will be recruited to implement, evaluate, and complete the project.

4.4.5. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed project.

4.4.6. Resubmission Summary

Use the template provided on the CARS (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. The overall summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.4.7. CPRIT Grants Summary

Use the template provided on the CARS (https://CPRITGrants.org). Provide a listing of **all** CPRIT-funded projects of the PD and the Co-PD, regardless of their connection to this application.

4.4.8. Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications

requesting more than the maximum allowed cost (total costs) as specified in section 2.9 will be administratively withdrawn.

- **Personnel:** The individual salary cap for CPRIT awards is $200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.
- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.9. Current and Pending Support and Sources of Funding

Use the template provided on the CARS (https://CPRITGrants.org). Describe the funding source and duration of **all** current and pending support for the proposed project, including a capitalization table that reflects private investors, if any. Information for the initial funded project need not be included.

4.4.10. Biographical Sketches

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

Up to 3 additional biographical sketches for key personnel may be provided. The evaluation professional biographical sketch is optional and will count as 1 of the 3 additional biosketches.

Each biographical sketch must not exceed 2 pages and must use the "Prevention Programs: Biographical Sketch" template provided on the CARS (https://CPRITGrants.org).

Only biographical sketches will be accepted; do not submit resumes and/or CVs.

4.4.11. Collaborating Organizations

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (eg, evaluation).

4.4.12. Letters of Commitment (10 pages)

Applicants may provide optional letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program.

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed and scored by the CPRIT Prevention Review Council based on the criteria in section 5.2 below. Review Council members are listed on CPRIT's website.

Applications may be submitted continuously in response to this RFA and will generally be reviewed twice per year (see section 3). The Prevention Review Council will review applications and provide an overall evaluation score reflecting their overall impression of the application and responsiveness to the RFA priorities. Additional considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service.

Applications approved by the Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 through 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Prevention Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2. Review Criteria

The Prevention Review Council will review the applications based on the criteria below and will provide an overall evaluation score reflecting their overall impression of the application and responsiveness to the RFA priorities. Additional considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service.

5.2.1. Primary Evaluation Criteria

Impact

- Does the applicant describe the project to be disseminated and how and why it lends itself to replication and scalability?
- Does the applicant outline the target metrics established for the CPRIT-funded project and describe the effectiveness of the intervention that is being proposed for replication/dissemination?
- Do the data (results) demonstrate success of the CPRIT-funded project and justify dissemination?
- Has the applicant convincingly demonstrated the short- and long-term impacts of the project?

Project Strategy and Feasibility

- Does the proposed project address the requirements of the RFA? Does it include a step-by-step implementation guide in Year 1?
- Are the overall project dissemination approach, strategy, and design clearly described and supported by established theory and practice and likely to result in successful dissemination and adoption? Are 2 or more active dissemination strategies described?
- Are the proposed objectives and activities feasible within the duration of the award?
- If the CPRIT-funded project is to be adapted for different populations and settings, are specific adaptations and evaluation strategies clearly outlined as a part of the project?
- Does the project identify and assist potential adopters in preparing to implement the intervention and/or preparing to apply for grant funding?

Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed measures appropriate for the project?
- Does the application provide a clear and appropriate plan for data collection and interpretation of results to report against goals and objectives?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners (if applicable) demonstrate the ability to deliver the proposed project?

- Are the appropriate personnel in place or have they been recruited to develop, evaluate, and complete the project?

5.2.2. Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope of the proposed work?
- Are all costs well justified?
- Is the project a good investment of Texas public funds?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal

reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide to using CARS.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

7.2. Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8417
Email: Help@CPRITGrants.org
Website: www.cprit.texas.gov

8. RESOURCES

- The Texas Cancer Registry. http://www.dshs.state.tx.us/tcr or contact the Texas Cancer Registry at the Department of State Health Services.
- The Community Guide. http://www.thecommunityguide.org/index.html
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, R.C., Colditz G.A., and Proctor, E.K. (Editors). *Dissemination and Implementation Research in Health: Translating Science to Practice.* Oxford University Press, March 2012

- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Getting the Word Out: New Approaches for Disseminating Public Health Science; Brownson, R.C., et al, *Journal of Public Health Management & Practice*. 24(2):102-111, March/April 2018. https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out___New_Approaches_for.4.aspx

APPENDIX: WRITING GOALS AND OBJECTIVES

Adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604

Develop well-defined goals and objectives

Goals provide a roadmap or plan for where a group wants to go. Goals can be long term (over several years) or short term (over several months). Goals should be based on needs of the community and evidence-based data.

Goals should be

- Believable – situations or conditions that the group believes can be achieved
- Attainable – possible within a designated time
- Tangible – capable of being understood or realized
- On a timetable – with a completion date
- Win-Win – beneficial to individual members and the coalition

Objectives are measurable steps toward achieving the goal. They are clear statements of specific activities required to achieve the goal. The best objectives have several characteristics in common—S.M.A.R.T. + C:

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)
    - Example: 115 uninsured individuals age 50 and older will complete colorectal cancer screening by March 31, 2019.
- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective
    - Example: How many screened at an event? How many completed pre/post assessment?
- Achievable – not only are the objectives themselves possible, it is likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved

- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

Review your developed objectives and determine the type and level of each using the following information:

There are 2 types of objectives:

- Outcome objectives – measure the "what" of a program; should be in the Goals and Objectives form (see section 4.4.2)
- Process objectives – measure the "how" of a program; should be in the project plan (see section 4.4.4)

There are 3 levels of objectives:

- Community-level – objectives measure the planned community change
- Program impact – objectives measure the impact the program will have on a specific group of people
- Individual – objectives measure participant changes resulting from a specific program, using these factors:
  - Knowledge – understanding (know screening guidelines; recall the number to call for screening)
  - Attitudes – feelings about something (will consider secondhand smoke dangerous; believe eating 5 or more fruits and vegetables is important)
  - Skills – the ability to do something (complete fecal occult blood test)
  - Intentions – regarding plan for future behavior (will agree to talk to the doctor, will plan to schedule a Pap test)
  - Behaviors (past or current) – to act in a particular way (will exercise 30+ minutes a day, will have a mammogram)

Well-defined goals and objectives can be used to track, measure, and report progress toward achievement.

Summary Table

	Outcome – Use in Goals and Objectives	Process – Use in Project Plan only
Community-level	WHAT will change in a community ***Example:*** *As a result of CPRIT funding, FIT (fecal immunochemical tests) will be available to 1,500 uninsured individuals age 50 and over through 10 participating local clinics and doctors.*	HOW the community change will come about ***Example:*** *Contracts will be signed with participating local providers to enable uninsured individuals over age 50 to have access to free colorectal cancer screening in their communities.*
Program Impact	WHAT will change in the target group as a result of a particular program ***Example:*** *As a result of this project, 200 uninsured women between 40 and 49 will receive free breast and cervical cancer screening.*	HOW the program will be implemented to affect change in a group/population ***Example:*** *2,000 female clients, between 40 and 49, will receive a letter inviting them to participate in breast and cervical cancer screening.*
Individual	WHAT an individual will learn as a result of a particular program, or WHAT change an individual will make as a result of a particular program ***Example:*** *As a result of one-to-one education of 500 individuals, at least 20% of participants will participate in a smoking cessation program to quit smoking.*	HOW the program will be implemented to affect change in an individual's knowledge or actions ***Example:*** *As a result of one-to-one counseling, all participants will identify at least 1 smoking cessation service and 1 smoking cessation aid.*

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT) Dissemination of CPRIT-Funded Cancer Control Interventions Meeting (19.1_PRV_DI) Prevention Review Observation Report

Report No.	2019-01-11 19.1_PRV_DI
Program Name:	Prevention
Panel Name:	Dissemination of CPRIT-Funded Cancer Control Interventions Meeting (19.1_PRV_DI)
Panel Date:	01-11-2019
Report Date:	01-15-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Dissemination of CPRIT-Funded Cancer Control Interventions Meeting (19.1_PRV_DI) meeting. The meeting was chaired by Stephen Wyatt and conducted via teleconference on January 11, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed
- Panelists: One (1) panel chair and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

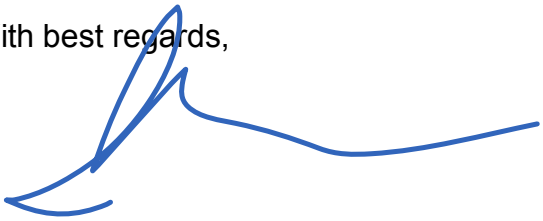
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Prevention Review Council Programmatic Review Meeting
(19.1_PRV_PRC)
Observation Report

Report No.	2019-01-11 19.1_PRV_PRC
Program Name:	Prevention
Panel Name:	Prevention Review Council Programmatic Review Meeting (19.1_PRV_PRC)
Panel Date:	01-11-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Prevention Review Council Programmatic Review Meeting (19.1_PRV_PRC). The meeting was chaired by Stephen Wyatt and conducted via teleconference on January 11, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and one (1) Dissemination mechanism project was added into the funding and rank order discussion
- Panelists: One (1) panel chair and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. One reviewer with two declared (2) COIs was not a member of the review council and thus not present for this meeting. One reviewer with two (2) COIs was excluded from discussions concerning one application for which there was a conflict, but not the other.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

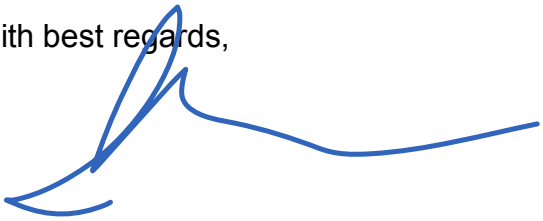
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Prevention 19.1 Applications
(Prevention Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 19.1 include *Evidence Based Cancer Prevention Services, Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations,* and *Tobacco Control and Lung Cancer Screening.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
PP190014	Kathleen Schmeler	The University of Texas M. D. Anderson Cancer Center	H. Brandt; R. Brownson
Applications not considered by the PIC or Oversight Committee			
PP190029	Lara Savas	The University of Texas Health Science Center at Houston	H. Brandt; R. Brownson

De-Identified Overall Evaluation Scores

Dissemination of CPRIT-Funded Cancer Control Interventions

Prevention Cycle 19.1

Application ID	Final Overall Evaluation Score
PP190041*	2.0
ra	5.7

* Recommended for award

Final Overall Evaluation Scores and Rank Order Scores

Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com
Via email to Will Montgomery assistant, Laura Blevins, lblevins@jw.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Roberts and Mr. Montgomery,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2019.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants.

The funding available for the fiscal year 2019 is $28,022,956. These recommended projects total $12,328,462.

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC continued to consider the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

Prevention Review Council Recommendations January 11, 2019											
Application ID	**Mechanism**	**Type**	**Application Title**	**PD**	**Organization**	**Total Requested Budget**	**Average Overall Score**	**Standard Deviation**	**Rank Order**	**Comments**	**Rec Budget**
PP190009	TCL	Resubmission	Expanding Tobacco Use Cessation in Northeast Texas	Prokhorov, Alexander V	The University of Texas M. D. Anderson Cancer Center	$1,499,956	2.1	0.6	1	Potential for Impact/Return on Investment and Type of	$1,499,956
PP190027	TCL	New	Engaging Oral Health Providers for Evidence-Based Tobacco Cessation	Jones, Daniel L	Texas A&M University System Health Science Center	$1,499,871	2.7	1.0	2	Potential for Impact/Return on Investment and Type of Program-Tobacco Control	$1,499,871
PP190004	EPS	Resubmission	Partnering with schools and clinics to expand a highly successful HPV vaccination program for 9-17 year olds from Medically Underserved Areas	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$2,499,411	1.5	0.5	3		$2,499,411
PP190021	EPS	New	Access to Breast and Cervical Care for west Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	$2,430,998	1.6	0.5	4		$2,430,998
PP190023	EPS	New	School-based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuation and Expansion to Hidalgo County	Rodriguez, Ana M	The University of Texas Medical Branch at Galveston	$1,969,731	1.9	0.3	5		$1,969,731
PP190014	EPS	New	Expansion of cervical cancer prevention services to medically underserved populations through patient outreach, navigation & provider training/telementoring	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	$2,128,529	2.6	0.8	6	Type of Program (EPS versus DI) and Potential for Impact/Return on Investment	$2,128,529
PP190041	DI	Resubmission	Adolescent Vaccination Program: Online Decision Support for Adoption of Evidence-based HPV Vaccination Strategies by Texas Pediatric Clinics	Shegog, Ross	The University of Texas Health Science Center at Houston	$299,966	2.0	0.0	7		$299,966

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA P-19.1-EPS

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

Please also refer to the Instructions for Applicants document, which will be posted on June 7, 2018

Application Receipt Opening Date: June 7, 2018
Application Receipt Closing Date: September 5, 2018

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 05/10/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1 Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary, and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize underserved populations

2. FUNDING OPPORTUNITY DESCRIPTION

2.1 Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer.

The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT fosters the prevention of cancer in Texas by providing financial support for a wide variety of evidence-based prevention interventions.

This award mechanism seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models to prevent and control these cancers.

Eligible applicants include only those with currently or previously funded CPRIT Prevention projects). Currently funded projects must be in their final year and programs must have at least 1 full year of data to report before applying. Eligible applicants should propose to expand their programs to include additional types of prevention clinical services or to expand current clinical services into additional counties. In either case, the expansion must include the delivery of services to nonmetropolitan (rural) and/or medically underserved counties in the state. These may be identified via Web-based tools from the Texas Department of State Health Services and US Department of Health and Human Services respectively (see below).

Health Facts Profiles
Non-Metropolitan Counties, 2013

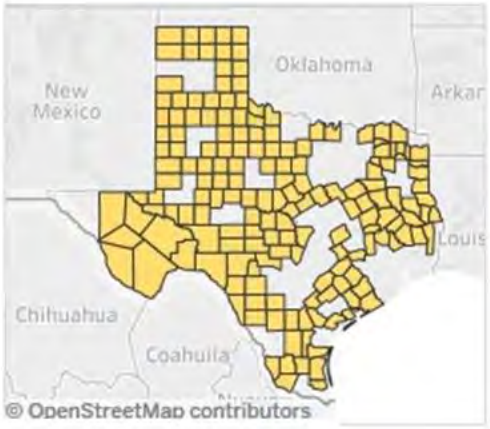
Demography / Population

Estimated Total Population
3,054,751

Number of Counties
172

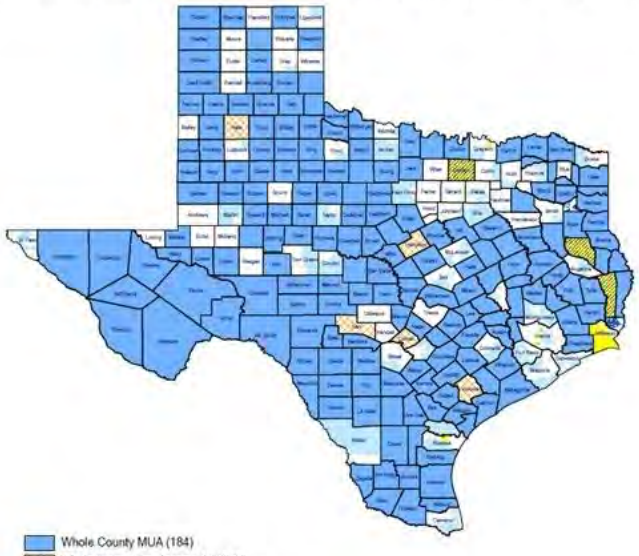
Area in Square Miles
184,738.9

Population per Square Mile
16.5



Data source: Center for Health Statistics, Texas Department of State Health Services

Texas Medically Underserved Areas (MUA) and Populations (MUP)



Map prepared by Texas Primary Care Office
Texas Department of State Health Services

Data source: US Health Resources and Services Administration Data Warehouse, October 2016

2.2 Project Objectives

CPRIT seeks to fund evidence-based prevention projects that will do the following:

- Expand an eligible CPRIT project by adding and integrating the delivery of 1 or more of the following to an existing project:
    - Screenings and diagnostics for breast, cervical, colorectal cancers; hepatitis C virus; genetic risk factors
    - Vaccinations against HPV and hepatitis B virus
- Expand an eligible CPRIT project by adding and integrating the delivery of services to additional nonmetropolitan and/or medically underserved counties.
- Coordinate the resources (clinical service providers, community organizations, etc) in nonmetropolitan and medically underserved areas (MUAs) to increase the availability of services and, where providers are available, help connect people with their local health care providers.
- Leverage the infrastructure, networks, and resources that have been put in place by CPRIT supported projects while minimizing startup time.
- Deliver comprehensive projects comprising all of the following: public and/or professional education, outreach, delivery of clinical services, follow-up navigation, and system and/or policy improvements.
- Offer effective and efficient systems of delivery of prevention services based on the existing body of knowledge about, and evidence for, cancer prevention in ways that far exceed current performance in a given service area.
- Implement policy changes and/or system improvements that are sustainable over time (eg, decrease wait times between positive screen and diagnostic tests and treatment through improved navigation, reminder systems, etc) and treatment.

2.3 Award Description

CPRIT's **Expansion of Cancer Prevention Services** grants are intended to fund the expansion of eligible projects that have demonstrated exemplary success, as evidenced by progress reports and project evaluations, and desire to further enhance their impact on priority populations. Detailed descriptions of **established infrastructure**, **results, barriers, outcomes, and impact of the most recently funded project are required** (see outline of Project Plan, section 4.4.4).

Projects in the last year of a current grant or previously funded projects may apply for this expansion. Programs must have at least 1 full year of data to report before applying (see section 2.7 for eligibility criteria).

The following are required components of the project:

- **Expansion:** Expansion to nonmetropolitan/MUA counties and/or offering additional clinical services are required. To qualify for this Expansion RFA, CPRIT requires applicants to either add the delivery of 1 or more of the following clinical services to their project or to expand to additional nonmetropolitan and/or MUA counties.
    - Screenings for breast, cervical, colorectal cancers; hepatitis C virus; genetic risk factors
    - Vaccinations against HPV; hepatitis B virus
    - Expansion of eligible projects into nonmetropolitan/medically underserved geographic areas not well served by the CPRIT portfolio (see maps at http://www.cprit.texas.gov/prevention/cprit-portfolio-maps), will receive priority consideration.
- **Comprehensive Projects:** Comprehensive projects include a continuum of services and systems and policy changes and comprise all of the following: Public and/or professional education and training, outreach, delivery of screening and diagnostic services, follow-up navigation, data collection and tracking, and systems improvement.

This mechanism will fund case management/patient navigation to screening, to diagnostic testing, and to treatment. Applicants must ensure that there is access to treatment services for patients with cancers or precancers that are detected as a result of the project and must describe in detail the process for ensuring access to treatment services in their application.

Applicants should not request funds for any of the above components if these components are already being funded from other sources. If clinical services are being provided and paid by others, the applicant must explain and report on the outcomes and services that are delivered to the people navigated by the program.

- **Evidence Based**: CPRIT's service grants are intended to fund effective and efficient systems of delivery of prevention services based on the existing body of knowledge about and evidence for cancer prevention in ways that far exceed current performance in a given service area. The

provision of clinical services must comply with established and current national guidelines (eg, US Preventive Services Task Force [USPSTF], American Cancer Society, etc).

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data (eg, availability of resources and screening coverage) for the target population and target service region are required. If no baseline data exist, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline.

Clinical Service and Community Partner Networks. Applicants are encouraged to coordinate and describe a collaboration of clinical service providers and community partners that can deliver outreach, education, clinical, and navigation services to the most counties and the most people possible in a selected service region. Partnerships with other organizations that can support and leverage resources (ie, community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations, etc) are encouraged. Letters of commitment or memoranda of understanding describing their specific role in the partnership will strengthen the application. Leveraging of the infrastructure, existing networks and other resources that were established for the eligible CPRIT-funded project are expected and should be well described.

Project Coordination and Technical Assistance. The overall program should be directed and overseen by the Program Director (PD) who is responsible for establishing and managing the network. Responsibilities of the PD include the following:

- Establishing any necessary subcontracts or memoranda of understanding with project partners and clinical service providers;
- Regularly communicating with partners to discuss progress and barriers, resolve potential problems, and provide technical assistance as needed throughout the duration of the project;
- Meeting all reporting requirements. CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based services, changes in provider practice, systems changes, and cost-effectiveness.

If applicable, in cases where the project proposes to work with multiple clinical providers, the PD should facilitate the establishment of standard protocols for all clinical service providers in the network as well as standard systems, policies, and procedures for the participating clinical service providers and organizations. These may include, but are not limited to, patient tracking and timely followup of all abnormal screening results and/or diagnoses of cancer.

Under this RFA, CPRIT **will not** consider the following**:**

- **Continuation of currently funded projects.** Projects must include the required expansion criteria detailed in the RFA.
- **Projects focusing on tobacco prevention and/or cessation for any age or computerized tomography screening for lung cancer for ages 55 to 77.** Applicants with projects in these areas should apply under CPRIT's Tobacco Control and Lung Cancer Screening (TCL) RFA.
- **New evidence-based cancer prevention services projects;** these applicants should apply under CPRIT's Evidence-Based Cancer Prevention Services RFA.
- **Projects focusing on case management/patient navigation services through the treatment phase of cancer.**
- **Projects focused solely on counseling with no additional evidence-based clinical service.**
- **Resources for the treatment of cancer or viral treatment for hepatitis.**
- **Prevention/intervention research** (Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).

2.4 Priorities

Types of Cancer: Applications addressing the services listed in section 2.2 Project Objectives and that are responsive to this RFA will be considered for funding.

The Prevention Program's priorities for funding include the following:

Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence: While disparities and needs exist across the state, CPRIT will also prioritize applications proposing to serve geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence. For this RFA, projects must propose to

serve nonmetropolitan and/or medically underserved areas of the state. In addition, projects addressing areas of emphasis (see section 2.5) will receive priority consideration.

Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence: CPRIT programs must address underserved populations**.** Underserved populations are subgroups that are disproportionately affected by cancer. CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals;
- Medically unserved or underserved populations;
- Racial, ethnic, and cultural minority populations;
- Populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance with nationally recommended screening guidelines (more than 5 years for breast/cervical cancers).

The age of the priority population and frequency of screening for provision of clinical services described in the application must comply with established and current national guidelines (eg, USPSTF, American Cancer Society).

Geographic and Population Balance in Current CPRIT portfolio: At the programmatic level of review conducted by the Prevention Review Council (see section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see http://www.cprit.texas.gov/prevention/resources-for-cancer-prevention-and-control and http://www.cprit.texas.gov/funded-grants).

2.5 Specific Areas of Emphasis

Applications addressing any of the services listed in section 2.2 and that are responsive to this RFA will be considered. For those services, CPRIT has identified the following areas of emphasis for this cycle of awards.

Primary Prevention
HPV Vaccination
• Increasing access to, delivery of, and completion of the HPV vaccine regimen to males and females through evidence-based intervention efforts in all areas of the state.[1]
Liver Cancer
• Screening for HBV infection and HCV infection in populations at high risk of infection and 1-time screening for HCV infection in adults born between 1945 and 1965.
• Increasing screening rates in Public Health Region (PHR) 8, 10, and 11. Incidence rates are highest in PHR 8 and 11 while mortality rates are highest in PHR 10 and 11.[2]
Secondary Prevention - Screening and Early Detection Services
Colorectal Cancer
• Decreasing disparities in incidence and mortality rates of colorectal cancer in racial/ethnic populations. Blacks have the highest incidence and mortality rates, followed by non-Hispanic whites and Hispanics.[2]
• Increasing screening/detection rates in PHR 2, 4, and 5, where the highest rates of cancer incidence and mortality are found. • Decreasing incidence and mortality rates in nonmetropolitan counties. Incidence and mortality rates are higher in nonmetropolitan counties compared with metropolitan counties.[2]
Breast Cancer
• Decreasing disparities in mortality rates of breast cancer in racial/ethnic populations. The mortality rate is significantly higher in blacks than in other populations.[2]
• Increasing screening/detection rates in medically underserved areas of the state.
Cervical Cancer
• Decreasing disparities in incidence and mortality rates of cervical cancer in racial/ethnic populations. Hispanics have the highest incidence rates while blacks have the highest mortality rates.[2]
• Increasing screening/detection rates for women in PHR 2, 4, 8, and 11. Incidence is highest in Texas-Mexico border counties (PHR 8 and 11). The mortality rate is highest in PHR 2, 4, and 11.[2]

2.6 Outcome Metrics

Applicants are required to clearly describe their assessment and evaluation methodology. The applicant is required to describe final outcome measures for the project. Output measures that are associated with the final outcome measures should be identified and will serve as a measure of program activity effectiveness. Planned policy or system changes should be identified and the plan for qualitative analysis described. **Baseline data for each measure proposed are required**. In

addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to establish a baseline. Applicants are required to fully describe any planned systems or policy changes or improvements.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to the following:
  - Summary page, including narrative on project progress (required);
  - Services, other than clinical services, provided to the public/professionals;
  - Actions taken by people/professionals as a result of education or training;
  - Clinical services provided (county of residence of client is required); and
  - Precursors and cancers detected.

- Annual and final progress report sections include, but are not limited to, the following:
  - Key accomplishments, **including qualitative analysis of policy change and/or lasting systems change;**
  - Progress toward goals and outcome objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible individuals in a defined service area;
  - Materials produced and publications; and
  - Economic impact of the project.

2.7 Eligibility

- Eligible applicants include only those with currently or previously funded CPRIT Prevention projects. Currently funded projects must be in their final year and programs must have at least 1 full year of data to report before applying.
- To justify the expansion, applicants must leverage the infrastructure and networks of the most recently funded CPRIT project.

- Applicants may submit an expansion application before the end of the currently funded project but should time their submission during the last year of the current project to ensure minimal overlap of funding. Unexpended funds from the original project will not carry forward to the expansion project. To apply for an expansion of a current project, projects must have at least 1 full year of results and data.
- The applicant must be a Texas-based entity that previously received CPRIT funding through Prevention Program RFAs.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted.
- The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field and who resides in Texas during the time that the project is conducted.
- If the applicant or a partner is an existing DSHS contractor, CPRIT funds may not be used as a match, and the application must explain how this grant complements or leverages existing state and federal funds. DSHS contractors who also receive CPRIT funds must be in compliance with and fulfill all contractual obligations within CPRIT. CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor receiving funds from both entities.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not- for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel

listed on the grant application, or any officer or director of the grant applicant's organization, (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.

- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 6. All statutory provisions and relevant administrative rules can be found at http://www.cprit.texas.gov.

2.8 Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications

may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

2.9 Funding Information

Applicants may request any amount of funding from $1 million to $2.5 million over a maximum of 36 months. A significant expansion in the geographic area and/or clinical services provided and number of people served is required if requesting over $2 million. However, CPRIT expects most applicants to request funding well below the upper range. Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Grantees may request funds for travel for 2 project staff to attend CPRIT's biennial conference.

Requests for funds to support construction or renovation or requests to support lobbying will not be approved under this mechanism. Cost sharing for equipment purchases is encouraged.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT funding should not be used to replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

3. KEY DATES

RFA release	May 10, 2018
Online application opens	June 7, 2018, 7 AM central time
Application due	September 5, 2018, 4 PM central time
Application review	October 2018-January 2019
Award notification	February 2019
Anticipated start date	March 1, 2019

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1 *Instructions for Applicants* document

It is imperative that applicants read the accompanying instructions document for this RFA that will be available June 7, 2018 (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2 Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on June 7, 2018, and must be submitted by 4 PM central time on September 5, 2019. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3 Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4 Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details.

Submissions that are missing 1 or more components or do not meet the eligibility requirements may be administratively withdrawn without review.

4.4.1 Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need in the specific service area. Include rates of incidence, mortality, and screening in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the priority population to be served.
- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) reached and people (public and/or professionals) served.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.4.2 Goals and Objectives (700 characters each)

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include** process objectives; these should be described in the project plan only. Include the measure within the stated objective. The maximum number is 3 goals with 3 objectives each. Projects will be evaluated annually on progress toward outcome goals and objectives. See Appendix B for instructions on writing outcome goals and objectives.

A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. If a baseline has not been defined,

applicants are required to explain plans to establish baseline and describe method(s) of measurement.

4.4.3 Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3, and Months 1, 2, 3, etc, as applicable instead of specific months or years (eg, Year 1, Months 3-5). Month 1 is the first full month of the grant award.

4.4.4 Project Plan (12 pages; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below.

Background: Briefly present the rationale behind the proposed service, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the priority population. If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the priority population and target service area are required where applicable. Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are encouraged.

Goals and Objectives: Process objectives should be included in the project plan. Outcome goals and objectives will be entered in separate fields in CARS. However, if desired, outcome goals and objectives may be fully repeated or briefly summarized here. See Appendix B for instructions on writing goals and objectives.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Describe why this project is nonduplicative. Describe how the proposed project leverages the infrastructure, networks and resources that have been put in place by the most recently funded CPRIT project while minimizing startup time.

It is important to distinguish between Texas counties where the project proposes to deliver services and counties of residence of population served (see Appendix A for definitions and *Instructions for*

Applicants). Only counties with service delivery should be listed in the Geographic Area to be Served section of the application. Projecting counties of residence of population served is not required but may be described in the project plan.

Clearly demonstrate the ability to provide the proposed service and describe how results will be improved over baseline and the ability to reach the priority population. Describe any planned policy changes or system improvements. If clinical services are being paid for and provided by others, the applicant must explain and report on the outcomes and services that are delivered to the people navigated by the program. Applicants must also clearly and thoroughly describe plans to **ensure access to treatment** services should cancer be detected.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the plan for outcome and output measurements, including qualitative analysis of policy and system changes. Describe data collection and management methods, data analyses, and anticipated results. Evaluation and reporting of results should be headed by a professional who has demonstrated expertise in the field. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

Program Sustainability: CPRIT funds projects that target needs not sufficiently covered by other funding sources. As CPRIT approaches the end of its funding authority in 2022, program sustainability is of paramount importance. CPRIT acknowledges that full maintenance and sustainability of CPRIT funded projects may not be feasible, especially in cases involving the delivery of clinical services. Educational and other less costly interventions may be more readily sustained. Full maintenance of a project, the ability of the grantee's setting or community to

continue to deliver the health benefits of the intervention as funded, is not required; however, efforts toward sustainability are expected and must be described. Program sustainability capacity is defined as the ability to maintain a program and its benefits over time.

Washington University in St Louis has developed a useful tool (Program Sustainability Assessment Tool) to assess program capacity for sustainability. They describe several factors that contribute to program sustainability. These factors include environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communication and strategic planning. Applicants are not required to use this tool; however, it provides practical guidance on factors that should be considered and should be included in the application to describe a program's capacity for sustainability.

It is expected that steps toward building sustainability capacity for the program will be taken and plans for such be fully described in the application. The applicant should assess and describe their current activities and capacity for sustainability and plans for sustainability beyond the project's end date.

Important factors to include in describing plans for sustainability include integration of the evidence-based intervention within the culture of the grantee's setting or community through policies and practices; plans for systems change that are sustainable over time (eg, improve provider practice, efficiency, cost-effectiveness); and activities (eg, training, identification of alternative resources, building internal assets) that build durable resources and enable the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention.

Dissemination and Replication: Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination efforts should consider the message, source, audience, and channel (Brownson, R.C., et al. *J Pub Health Manag Pract*. 24(2):102-111, March/April 2018). Dissemination methods may include, but are not limited to, presentations at workshops and seminars, one-on-one meetings, publications, news media, social media, etc.

While passive dissemination methods are common (eg, publications, presentations at professional meetings), plans should include some active dissemination methods (eg, meetings with stakeholders, blogs, social media.) Applicants should describe their dissemination plans. The plans

should include the kinds of audiences to be targeted and methods for reaching the targeted audiences.

Replication by others is an additional way to disseminate the project. For applicable components, describe how the project or components of the project lend themselves to application by other communities and/or organizations in the state or expansion in the same communities. Describe what components of this project can be adapted to a larger or lower resource setting. Note that some programs may have unique resources and may not lend themselves to replication by others.

4.4.5 People Reached (Indirect Contact)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the types of indirect noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to Appendix A for definitions.

4.4.6 Number of Services Delivered (Direct Contact)

Provide the estimated overall number of services directly delivered to members of the public and to professionals by the funded project. Each service should be counted, regardless of the number of services one person receives. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimate provided. Refer to Appendix A for definitions.

4.4.7 Number of Unique People Served (Direct Contact)

Provide the estimated overall number of unique members of the public and professionals served by the funded project. One person may receive multiple services but should only be counted once here. Refer to Appendix A for definitions.

4.4.8 References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed services.

4.4.9 Resubmission Summary

Use the template provided on the CARS (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the

application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. The overall summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.4.10 Most Recently Funded Project Summary (3 pages)

Upload a summary that outlines the progress made with the most recently funded CPRIT award. Applicants must describe and demonstrate how appropriate/adequate progress has been made on the most recently funded award to warrant expansion of the project.
Please note that a different set of reviewers from those assigned to the previously funded application may evaluate this application. Applicants should make it easy for reviewers to compare the most recently funded project with the proposed expansion project.

In the description include the following:

- Describe the evidence-based intervention, its purpose, and how it was implemented in the priority population. Describe any adaptations made for the population served.
- List approved goals and objectives of the most recently funded grant.
- For each objective, provide the following information:
    - Milestones/target dates and target metrics
    - Actual completion dates and metrics
- For the most recently funded project, describe major activities; significant results, including major findings, developments or conclusions (both positive and negative); and key outcomes. If the project has not yet ended, provide projections for completion dates and final metrics. Include a discussion of objectives not fully met. Explain any barriers encountered and strategies used to overcome these.
- Describe steps taken toward sustainability for components of the project. Fully describe systems or policy improvements and enhancements.
- Describe how project results were disseminated or plans for future dissemination of results.

4.4.11 CPRIT Grants Summary

Use the template provided on the CARS (https://CPRITGrants.org). Provide a listing of **all** CPRIT-funded projects of the PD and the Co-PD, regardless of their connection to this application.

4.4.12 Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in section 2.9 will be administratively withdrawn.

- **Average Cost per Service:** The average cost per services will be automatically calculated from the total cost of the project divided by the total number of services delivered (refer to Appendix A). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Personnel:** The individual salary cap for CPRIT awards is $200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.
- **Services Costs:**
  - CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested.
  - CPRIT does not allow recovery of costs related to tests that have not been recommended by the USPSTF. In several cases (eg, breast self-exams, clinical breast exams, PSA tests), the Task Force has concluded there is not enough evidence available to draw reliable conclusions about the additional benefits and harms of these tests. (See https://www.uspreventiveservicestaskforce.org/)

- **Other Expenses:**
  - **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is $25.
  - **Costs Not Related to Cancer Prevention and Control:** CPRIT does not allow recovery of any costs for services not related to cancer (eg, health physicals, HIV testing).
- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.13 Current and Pending Support and Sources of Funding

Use the template provided on the CARS (https://CPRITGrants.org). Describe the funding source and duration of **all** current and pending support for the proposed project, including a capitalization table that reflects private investors, if any.

4.4.14 Biographical Sketches

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

- Use the Co-PD Biographical Sketch section ONLY if a Co-PD has been identified.
- The evaluation professional must provide a biographical sketch in the Evaluation Professional Biographical sketch section.
- Up to 3 additional biographical sketches for key personnel may be provided in the Key Personnel Biographical Sketch section.

Each biographical sketch must not exceed 2 pages and should use the "Prevention Programs: Biographical Sketch" template provided on the CARS (https://CPRITGrants.org). Only biographical sketches will be accepted; do not submit resumes and/or CVs. If a position is not yet filled, please upload a job description.

4.4.15 Collaborating Organizations

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (eg, evaluation, clinical services, recruitment to screening).

4.4.16 Letters of Commitment (10 pages)

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program. Letters should be specific to the contribution of each organization.

5. APPLICATION REVIEW

5.1 Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels as well as programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT

Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules,** chapter 703, section 703.9**.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2 Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1 Primary Evaluation Criteria

Impact

- Do the proposed services address an important problem or need in cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Do the proposed project strategies reach a priority population (eg, low income, minority, rural) at high risk of cancer?
- For the proposed expansion, does the project build on its initial results (baseline)? Does it go beyond the initial project to address what the applicant has learned or explore new partnerships, new audiences, or improvements to systems?
- Will the project reach and serve/impact an appropriate number of people based on the budget allocated to providing services and the cost of providing services?
- If applicable, have partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than the applicant organization's effort separately?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the priority population? Is the base of evidence clearly explained and referenced?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall program approach, strategy, and design clearly described and supported by established theory and practice? Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Has the applicant proposed policy changes and/or system improvements?

- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including followup for abnormal results and access to treatment?
- Does the program leverage partners and resources to maximize the reach of the services proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- Does the application provide a clear and appropriate plan for data collection and management and data analyses?
- Are clear baseline data provided for the priority population, or are clear plans included to collect baseline data?
- If an evidence-based intervention is being adapted in a population where it has not been implemented or tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services? Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?

Program Sustainability

- Does the applicant describe the current activities and capacity for sustainability and plans for sustainability beyond the project's end date?
- Does the applicant describe steps that will be taken and components of the project that will be integrated into the organization through policies and practices?
- Does the applicant describe a plan for systems changes that are sustainable over time; eg, improve results, provider practice, efficiency, cost-effectiveness?
- Does the applicant describe steps that the applicant organization or other entities will take or components of the project that will remain (eg, trained personnel, identification of alternative resources, building internal assets) to continue the delivery of some or all components of the evidence-based intervention once CPRIT funding ends?

5.2.2 Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Replication

- Are plans for dissemination of the project's results and outcomes, including target audience and methods, clearly described?
- Are active dissemination strategies included and described in the plan?
- Does the applicant describe whether and/or how the project lends itself to replication of all or some components of the project by others in the state?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange,

execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1 Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the helpdesk, please refer to the *Instructions for Applicants* document (posted on June 7, 2018), which provides a step-by-step guide to using CARS.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

7.2 Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8417
Email: Help@CPRITGrants.org
Website: www.cprit.texas.gov

8. RESOURCES

- The Texas Cancer Registry. http://www.dshs.state.tx.us/tcr or contact the Texas Cancer Registry at the Department of State Health Services.
- The Community Guide. http://www.thecommunityguide.org/index.html
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, R.C., Colditz G.A., and Proctor, E.K. (Editors). *Dissemination and Implementation Research in Health: Translating Science to Practice.* Oxford University Press, March 2012

- Program Sustainability Assessment Tool, copyright 2012, Washington University, St Louis, MO (https://cphss.wustl.edu/Projects/Pages/Sustainability-Framework-and-Assessment-Tool.aspx)
- Getting the Word Out: New Approaches for Disseminating Public Health Science; Brownson, R.C., et al, *Journal of Public Health Management & Practice*. 24(2):102-111, March/April 2018. https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out___New_Approaches_for.4.aspx
- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs. http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

9. REFERENCES

1. http://www.cdc.gov/hpv/parents/questions-answers.html
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services. http://www.dshs.state.tx.us/tcr/default.shtm

APPENDIX A: KEY TERMS

- **Activities:** A listing of the "who, what, when, where, and how" for each objective that will be accomplished
- **Capacity Building**: Any activity (eg, training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention
- **Clinical Services:** Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- **Counties of Residence of Population Served:** Counties where the project does not plan to have a physical presence but people who live in these counties have received services. This includes counties of residence of people or places of business of professionals who participate in or receive education, navigation or clinical services. Examples include people traveling to receive services as a result of marketing, and programs accessible via the website or social media. These counties may be described in the project plan and must be reported in the quarterly progress report.
- **Counties with Service Delivery:** Counties where an activity or service will occur and the project has a physical presence for the services provided. Examples include onsite outreach and educational activities, and delivery of clinical services through clinics, mobile vans or telemedicine consults. These counties must be entered in the Geographic Area to be Served section of the application.
- **Education Services:** Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to health care professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments.

- **Evidence-Based Program:** A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit http://www.cprit.texas.gov/prevention/resources-for-cancer-prevention-and-control.
- **Goals:** Broad statements of general purpose to guide planning. Outcome goals should be few in number and focus on aspects of highest importance to the project.(Appendix B)
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice
- **Navigation Services:** Number of unique activities/services that offer assistance to help overcome health care system barriers in a timely and informative manner and facilitate cancer screening and diagnosis to improve health care access and outcomes (Examples include patient reminders, transportation assistance, and appointment scheduling assistance.)
- **Number of Services (Direct Contact):** Number of services delivered directly to members of the public and/or professionals—direct, interactive public or professional education, outreach, training, navigation service, or clinical service, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. Note that one individual may receive multiple services.
- **Objectives:** Specific, **measurable,** actionable, realistic, and timely projections for outcomes; example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the priority population must be included as part of each objective. (Appendix B)
- **People Reached (Indirect Contact):** Number of members of the public and/or professionals reached via indirect noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals (This category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project).

- **People Served (Direct Contact):** Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service, or clinical service. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.

APPENDIX B: WRITING GOALS AND OBJECTIVES

Adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604

Develop well-defined goals and objectives.

Goals provide a roadmap or plan for where a group wants to go. Goals can be long term (over several years) or short term (over several months). Goals should be based on needs of the community and evidence-based data.

Goals should be:

- Believable – situations or conditions that the group believes can be achieved
- Attainable – possible within a designated time
- Tangible – capable of being understood or realized
- On a timetable – with a completion date
- Win-Win – beneficial to individual members and the coalition

Objectives are measurable steps toward achieving the goal. They are clear statements of specific activities required to achieve the goal. The best objectives have several characteristics in common – S.M.A.R.T. + C:

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)
    - Example: 115 uninsured individuals age 50 and older will complete colorectal cancer screening by March 31, 2019.
- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective
    - Example: How many screened at an event? How many completed pre/post assessment?
- Achievable – not only are the objectives themselves possible, it is likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved

- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

Review your developed objectives and determine the type and level of each using the following information:

There are 2 types of objectives:

- Outcome objectives – measure the "what" of a program; should be in the Goals and Objectives form (see section 4.4.2)
- Process objectives – measure the "how" of a program; should be in the project plan only (see section 4.4.4)

There are 3 levels of objectives:

- Community-level – objectives measure the planned community change
- Program impact – objectives measure the impact the program will have on a specific group of people
- Individual – objectives measures participant changes resulting from a specific program, using these factors:
  - Knowledge – understanding (know screening guidelines; recall the number to call for screening)
  - Attitudes – feeling about something (will consider secondhand smoke dangerous; believe eating 5 or more fruits and vegetable is important)
  - Skills – the ability to do something (complete fecal occult blood test)
  - Intentions – regarding plan for future behavior (will agree to talk to the doctor, will plan to schedule a Pap test)
  - Behaviors (past or current) – to act in a particular way (will exercise 30+ minutes a day, will have a mammogram)

Well-defined outcome goals and objectives can be used to track, measure, and report progress toward achievement.

Summary Table

	Outcome – Use in Goals and Objectives	Process – Use in Project Plan only
Community-level	WHAT will change in a community ***Example:*** *As a result of CPRIT funding, FIT (fecal immunochemical tests) will be available to 1,500 uninsured individuals age 50 and over through 10 participating local clinics and doctors.*	HOW the community change will come about ***Example:*** *Contracts will be signed with participating local providers to enable uninsured individuals over age 50 have access to free colorectal cancer screening in their communities.*
Program impact	WHAT will change in the target group as a result of a particular program ***Example:*** *As a result of this project, 200 uninsured women between 40 and 49 will receive free breast and cervical cancer screening.*	HOW the program will be implemented to affect change in a group/population ***Example:*** *2,000 female clients, between 40 and 49, will receive a letter inviting them to participate in breast and cervical cancer screening.*
Individual	WHAT an individual will learn as a result of a particular program, or WHAT change an individual will make as a result of a particular program ***Example:*** *As a result of one-to-one education of 500 individuals, at least 20% of participants will participate in a smoking cessation program to quit smoking.*	HOW the program will be implemented to affect change in an individual's knowledge or actions ***Example:*** *As a result of one-to-one counseling, all participants will identify at least 1 smoking cessation service and 1 smoking cessation aid.*

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Prevention Peer Review Meeting Panel 1
(19.1_PRV_ Panel PP-1)
Observation Report

Report No.	2018 – 12 – 12 19.1_PRV_ Panel PP-1
Program Name:	Prevention
Panel Name:	Prevention Peer Review Meeting Panel 1 (19.1_PRV_ Panel PP-1)
Panel Date:	12-11-2018 and 12-12-18
Report Date:	12-14-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Prevention Peer Review Meeting Panel 1 (19.1_PRV_ Panel PP-1) meeting. The meeting was chaired by Ross Brownson and Nancy Lee and conducted via in-person on December 11, 2018 and December 12, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Sixteen (16) applications were discussed and four (4) were not discussed
- Panelists: Two (2) panel chairs and eleven (11) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Six (6)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

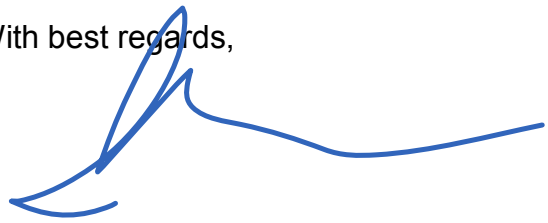
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Prevention Review Council Programmatic Review Meeting
(19.1_PRV_PRC)
Observation Report

Report No.	2019-01-11 19.1_PRV_PRC
Program Name:	Prevention
Panel Name:	Prevention Review Council Programmatic Review Meeting (19.1_PRV_PRC)
Panel Date:	01-11-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Prevention Review Council Programmatic Review Meeting (19.1_PRV_PRC). The meeting was chaired by Stephen Wyatt and conducted via teleconference on January 11, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and one (1) Dissemination mechanism project was added into the funding and rank order discussion
- Panelists: One (1) panel chair and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. One reviewer with two declared (2) COIs was not a member of the review council and thus not present for this meeting. One reviewer with two (2) COIs was excluded from discussions concerning one application for which there was a conflict, but not the other.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

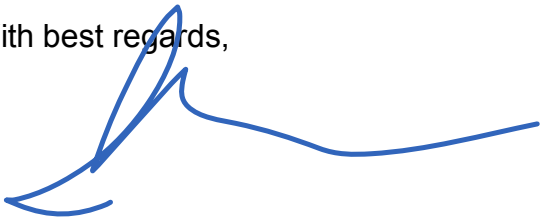
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Prevention 19.1 Applications
(Prevention Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 19.1 include *Evidence Based Cancer Prevention Services, Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations,* and *Tobacco Control and Lung Cancer Screening.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
PP190014	Kathleen Schmeler	The University of Texas M. D. Anderson Cancer Center	H. Brandt; R. Brownson
Applications not considered by the PIC or Oversight Committee			
PP190029	Lara Savas	The University of Texas Health Science Center at Houston	H. Brandt; R. Brownson

De-Identified Overall Evaluation Scores

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

Prevention Cycle 19.1

At their meeting on January 11, 2019, the Prevention Review Council (PRC) recommended four applications from this mechanism. All four of these applications were recommended ahead of an application with either the same or more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio

Application ID	Final Overall Evaluation Score
PP190004*	1.5
sa	1.5
PP190021*	1.6
PP190023*	1.9
PP190014*	2.6
sb	4.0
Sc	4.1

* Recommended for award

Final Overall Evaluation Scores and Rank Order Scores

Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com
Via email to Will Montgomery assistant, Laura Blevins, lblevins@jw.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Roberts and Mr. Montgomery,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2019.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants.

The funding available for the fiscal year 2019 is $28,022,956. These recommended projects total $12,328,462.

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC continued to consider the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

Prevention Review Council Recommendations January 11, 2019											
Application ID	**Mechanism**	**Type**	**Application Title**	**PD**	**Organization**	**Total Requested Budget**	**Average Overall Score**	**Standard Deviation**	**Rank Order**	**Comments**	**Rec Budget**
PP190009	TCL	Resubmission	Expanding Tobacco Use Cessation in Northeast Texas	Prokhorov, Alexander V	The University of Texas M. D. Anderson Cancer Center	$1,499,956	2.1	0.6	1	Potential for Impact/Return on Investment and Type of	$1,499,956
PP190027	TCL	New	Engaging Oral Health Providers for Evidence-Based Tobacco Cessation	Jones, Daniel L	Texas A&M University System Health Science Center	$1,499,871	2.7	1.0	2	Potential for Impact/Return on Investment and Type of Program-Tobacco Control	$1,499,871
PP190004	EPS	Resubmission	Partnering with schools and clinics to expand a highly successful HPV vaccination program for 9-17 year olds from Medically Underserved Areas	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$2,499,411	1.5	0.5	3		$2,499,411
PP190021	EPS	New	Access to Breast and Cervical Care for west Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	$2,430,998	1.6	0.5	4		$2,430,998
PP190023	EPS	New	School-based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuation and Expansion to Hidalgo County	Rodriguez, Ana M	The University of Texas Medical Branch at Galveston	$1,969,731	1.9	0.3	5		$1,969,731
PP190014	EPS	New	Expansion of cervical cancer prevention services to medically underserved populations through patient outreach, navigation & provider training/telementoring	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	$2,128,529	2.6	0.8	6	Type of Program (EPS versus DI) and Potential for Impact/Return on Investment	$2,128,529
PP190041	DI	Resubmission	Adolescent Vaccination Program: Online Decision Support for Adoption of Evidence-based HPV Vaccination Strategies by Texas Pediatric Clinics	Shegog, Ross	The University of Texas Health Science Center at Houston	$299,966	2.0	0.0	7		$299,966

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Individual Investigator Research Awards

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-19.1-IIRA

Individual Investigator Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on March 7, 2018

Application Receipt Opening Date: March 7, 2018

Application Receipt Closing Date: June 6, 2018

FY 2019
Fiscal Year Award Period
September 1, 2018–August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 1/11/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas (liver cancers)

2. RATIONALE

The goals of the CPRIT Academic Research Grants Program are to support the discovery of new information about cancer that can lead to prevention, early detection, and cures and to translate new and existing discoveries into practical advances in cancer diagnosis and treatment. CPRIT encourages applications that seek new fundamental knowledge about cancer and cancer development as well as those attempting to develop state-of-the-art technologies, tools, computational models, and/or resources for cancer research, including those with potential commercialization opportunities. This award allows experienced or early-career-stage cancer researchers the opportunity to explore new methods and approaches for investigating a question of importance that has been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. CPRIT will look with special favor on new approaches to be taken or new areas of investigation to be explored by established investigators and on supporting the research programs of the most promising investigators at the beginning of their research careers. Applicants need not be trained specifically in cancer research. Indeed, CPRIT strongly encourages investigators from other fields, including the mathematical and computational modeling, physical, chemical, and engineering sciences, to bring their expertise to bear on the exceptionally challenging problems posed by cancer. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer, including cancer biology, computational modeling, and systems biology, causation, prevention, detection or screening, treatment, or cure. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies. Access to a clinical environment and interaction with translational cancer physician-scientists are highly desirable.

3. RESEARCH OBJECTIVES

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This Request for Applications (RFA) solicits applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. The goal of awards made in response to this RFA is to fund exceptionally innovative research projects with great

potential impact that are directed by a single investigator. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Applications that include collaboration with computational modeling teams are encouraged. In that cancers arise from a large number of derangements of basic molecular and cellular functions and, in turn, cause many alterations in basic biological processes, almost any aspect of biology may be relevant to cancer research, more or less directly. The *degree of relevance* to cancer research is a critical criterion for evaluation of projects for funding by CPRIT (section 9.4.1). For example, are alterations in the process in question *primarily* responsible for oncogenesis or secondary manifestations of malignant transformation? Will understanding the process or interfering with it offer selective and useful insight into prevention, diagnosis, or treatment of cancer? *Successful applicants for funding from CPRIT will have addressed these questions satisfactorily.*

4. FUNDING INFORMATION

Applicants may request a maximum of $300,000 in total costs per year for up to 3 years for research. Exceptions to these limits may be requested if extremely well justified (see section 8.2.10). Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Research Program.
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.

- A PI may not submit applications to this RFA and to RFA-R-19.1-IIRACT, RFA-R-19.1-IIRACB, RFA-R-19.1-IIRACCA, or RFA R-19.1-IIRAP. Only 1 IIRA, IIRACT, IIRACB, IIRACCA, or IIRAP application per cycle is allowed. A PI may submit only 1 new or resubmission application under this RFA during this funding cycle. If submitting a renewal application, a PI may submit both a new or resubmission application and a renewal application under this RFA during this funding cycle.
- A PI may be a Co-PI on applications submitted to this RFA and to RFA-R-19.1-IIRACT, RFA-R-19.1-IIRACB, RFA-R-19.1-IIRACCA, or RFA R-19.1-IIRAP.
- An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants. Recruitment Grants and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers MIRA Project Co-PIs equivalent to a PI. For the purpose of calculating the number of active grants, CPRIT will consider the number of active grants at the time of the award contract effective date (for this cycle expected to be March 1, 2019).
- Applications that address Prevention and Early Detection, Cancers in Children and Adolescents, Clinical Translation, or Computational Biology should be submitted under the appropriate targeted RFA.
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included.
- Collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity) has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the

grant applicant's organization or institution is related to a CPRIT Oversight Committee member.

- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. This policy is in effect for all applications submitted to date. See section 8.2.5.

7. RENEWAL POLICY

An application funded by CPRIT under this mechanism may be submitted for a competitive renewal. This policy is in effect for all awards submitted to date. See section 8.2.6. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See section 9.2.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 7, 2018, and must be submitted by 4 PM central time on June 6, 2018. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk, within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records. Please note that deadline extension requests are very rarely approved.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 5 will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. **Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see** section 9.1**).** Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan.

Clearly address how the proposed project, if successful, will have a major impact on cancer.

Summarize how the proposed research creates new paradigms or challenges existing ones.

Indicate whether this research plan represents a new direction for the PI.

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the layperson's summary. The layperson's summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications.

If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (2 pages)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh research plan or modify the original research plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

8.2.8. Vertebrate Animals and/or Human Subjects (2 pages)

If vertebrate animals will be used, provide a detailed plan of the protocols that will be followed. If human subjects or human biological samples will be used, provide a detailed plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism. If vertebrate animals and/or human subjects are included in the proposed research, reference biostatistical input for sample selection and evaluation. In addition, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding

indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2019 is $200,000; CPRIT FY 2019 is from September 1, 2018, through August 31, 2019. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. Biographical Sketches (5 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

8.2.12. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.13. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.14. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

8.3. Formatting Instructions

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English.
- **Document Format:** PDF only.
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Line Spacing:** Single.
- **Page Size:** 8.5 x 11 inches.
- **Margins:** 0.75 inch, all directions.
- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.

- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. Include URLs of publications referenced in the application.

  Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135: 45–67.

- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments

made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed in section 9.4. Applicants will be notified of peer review panel assignments prior to the peer review meeting dates. Peer review panel membership can be found on the CPRIT website. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Research Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and expertise to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage-specific fashion. Have early-career-stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percent effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This is a critical criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: Is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed?

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA	
RFA release	January 11, 2018
Application	
Online application opens	March 7, 2018, 7 AM central time
Application due	June 6, 2018, 4 PM central time
Application review	August–October 2018
Award	
Award notification	February 20, 2019
Anticipated start date	March 1, 2019

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal

monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. A grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the 5% indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time.

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Academic Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-1 Peer Review Meeting
(19.1_ACR_BCR-1)
Observation Report

Report No.	2018-10-19 19.1_ACR_BCR-1
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-1_Peer Review Meeting (19.1_ACR_BCR-1)
Panel Date:	10-19-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-1_Peer Review (19.1_ACR_BCR-1) meeting. The meeting was chaired by Thomas Curran and conducted via in-person in Dallas, Texas on October 19, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and eighteen (18) were not discussed
- Panelists: One (1) panel chair and fourteen (14) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

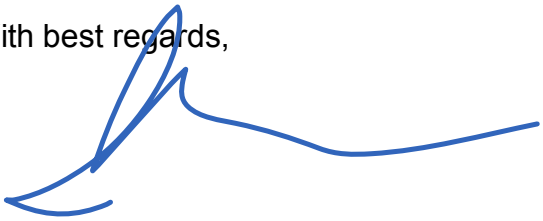
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-2 Peer Review Meeting
(19.1_ACR_BCR-2)
Observation Report

Report No.	2018-10-23 19.1_ACR_BCR-2
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-2_Peer Review Meeting (19.1_ACR_BCR-2)
Panel Date:	10-23-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-2_Peer Review (19.1_ACR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via in-person in Dallas, Texas on October 23, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and fifteen (15) were not discussed
- Panelists: One (1) panel chair and seventeen (17) expert reviewers and one (1) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and two (2) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

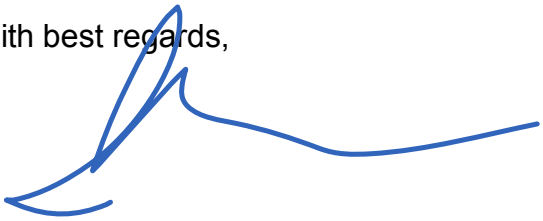
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Biology Peer Review Meeting (19.1 ACR CB)
Observation Report

Report No.	2018-10-22 19.1_ACR_CB
Program Name:	Academic Research
Panel Name:	Cancer Biology Peer Review Meeting (19.1_ACR_CB)
Panel Date:	10/22/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Biology Peer Review (19.1_ACR_CB) meeting. The meeting was chaired by Peter Jones and conducted via in-person in Dallas, Texas on October 22, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and nineteen (19) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were five (5) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

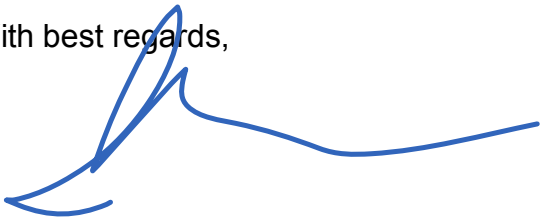
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Prevention Research Peer Review Meeting
(19.1_ACR_CPR)
Observation Report

Report No.	2018-10-24 19.1_ACR_CPR
Program Name:	Academic Research
Panel Name:	Cancer Prevention Research Peer Review Meeting (19.1_ACR_CPR)
Panel Date:	10/24/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Prevention Research Peer Review (19.1_ACR_CPR) meeting. The meeting was chaired by Thomas Sellars and conducted via in-person in Dallas, Texas on October 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eighteen (18) applications were discussed and fourteen (14) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eighteen (18) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

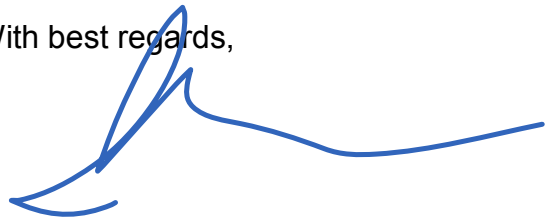
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Clinical/Translational Cancer Research Peer Review Meeting
(19.1 ACR C/TCR)
Observation Report

Report No.	2018-10-25 19.1_ACR_C/TCR
Program Name:	Academic Research
Panel Name:	Clinical/Translational Cancer Research Peer Review Meeting (19.1_ACR_C/TCR)
Panel Date:	10/25/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Clinical/Translational Cancer Research Peer Review (19.1_ACR_C/TCR) meeting. The meeting was chaired by Margaret Tempero and Richard O'Reilly and conducted via in-person in Dallas, Texas on October 25, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and twenty-one (21) were not discussed
- Panelists: Two (2) panel chairs, twenty-three (23) expert reviewers and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were ten (10) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

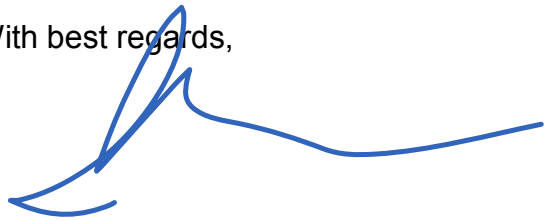
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Imaging Technology and Informatics Review Meeting
(19.1_ACR_ITI)
Observation Report

Report No.	2018-10-18 19.1_ACR_ITI
Program Name:	Academic Research
Panel Name:	Imaging Technology and Informatics Review Meeting (19.1_ACR_ITI)
Panel Date:	10/18/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Imaging Technology and Informatics Review Meeting (19.1_ITI) meeting. The meeting was chaired by Sanjiv Sam Gambhir and conducted via in-person in Dallas, Texas on October 18, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seventeen (17) applications were discussed and twenty-one (21) were not discussed
- Panelists: One (1) panel chair and twenty (20) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

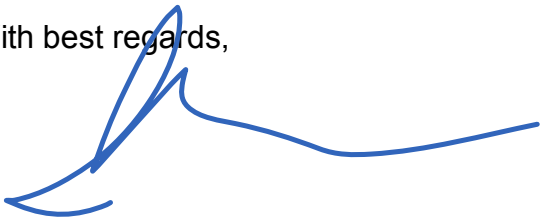
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)

19.1 Scientific Review Council Meeting (19.1 SRC) Observation Report

Report No. 2018-12-05 19.1_SRC
Program Name: Academic Research
Panel Name: 19.1 Scientific Review Council Meeting (19.1_SRC)
Panel Date: 12/05/2018
Report Date: 12/05/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Scientific Review Council Meeting (19.1_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via or teleconference on December 5, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Forty-seven (47) applications were discussed and zero (0) were not discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

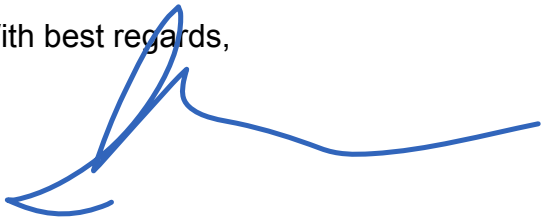
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Academic Research 19.1 Applications
(Academic Research Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 19.1 include *Individual Investigator Research Awards, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Clinical Translation, Individual Investigator Research Awards for Computational Biology,* and *Individual Investigator Research Awards for Prevention and Early Detection.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP190414pe/ RP190414	David McFadden	The University of Texas Southwestern Medical Center	M. McMahon
RP190077pe/ RP190077	Cheng-Ming Chiang	The University of Texas Southwestern Medical Center	T. Kodadek
RP190301pe	Ilya Finkelstein	The University of Texas at Austin	A. Tomkinson;C. Prives;W. Chazin
RP190301	Ilya Finkelstein	The University of Texas at Austin	J. Manley
RP190421pe/ RP190421	Elizabeth Goldsmith	The University of Texas Southwestern Medical Center	A. Tomkinson;T. Kodadek
RP190398pe	Rachel Schiff	Baylor College of Medicine	G. Greene
RP190398	Rachel Schiff	Baylor College of Medicine	A. Tonachel;G. Greene
RP190210pe/ RP190210	Robert Volk	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon

Application ID	Applicant/PI	Institution	Conflict Noted
RP190326pe/ RP190326	Roza Nurieva	The University of Texas M. D. Anderson Cancer Center	S. Dubinett;V. Engelhard
RP190019pe/ RP190019	Eva Sevick	The University of Texas Health Science Center at Houston	A. Wu
RP190211pe/ RP190211	Mark Pagel	The University of Texas M. D. Anderson Cancer Center	J. Basilion
Applications not considered by the PIC or Oversight Committee			
RP190464pe/ RP190464	Everett Stone	The University of Texas at Austin	G. Prendergast
RP190087pe/ RP190087*	John Tainer	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson;W. Chazin
RP190203pe/ RP190203*	Pawel Mazur	The University of Texas M. D. Anderson Cancer Center	N. Bardeesy
RP190314pe	Jason Huse	The University of Texas M. D. Anderson Cancer Center	J. Petrini
RP190332pe/ RP190332*	Steven Millward	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson
RP190078pe/ RP190078*	Ralf Krahe	The University of Texas M. D. Anderson Cancer Center	J. Issa
RP190245pe	Yunfei Wen	The University of Texas M. D. Anderson Cancer Center	M. Hollingsworth
RP190356pe/ RP190356*	Jung-whan Kim	The University of Texas at Dallas	M. Hollingsworth
RP190458pe/ RP190458	Robert Chapkin	Texas AgriLife Research	E. Fearon
RP190039pe/ RP190039*	Divya Patel	The University of Texas Health Center at Tyler	T. Brandon
RP190044pe/ RP190044	Jason Robinson	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190054pe/ RP190054	Sheng Pan	The University of Texas Health Science Center at Houston	C. Li;G. Petersen;W. Barlow

Application ID	Applicant/PI	Institution	Conflict Noted
RP190062pe/ RP190062	Wenyi Wang	The University of Texas M. D. Anderson Cancer Center	L. Mucci
RP190068pe/ RP190068*	Jian Gu	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190139pe/ RP190139	Alexander Prokhorov	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190232pe/ RP190232*	Manal Hassan	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190281pe	Olena Weaver	The University of Texas M. D. Anderson Cancer Center	C. Li
RP190321pe/ RP190321*	Lindsay Cowell	The University of Texas Southwestern Medical Center	C. Li;W. Barlow
RP190357pe/ RP190357	Subrata Sen	The University of Texas M. D. Anderson Cancer Center	G. Petersen;W. Barlow
RP190479pe/ RP190479*	Xuexia Wang	University of North Texas	L. Kushi
RP190016pe	Damith Udugamasooriya	University of Houston	S. Dubinett
RP190148pe/ RP190148*	Chun Li	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190166pe/ RP190166*	Khandan Keyomarsi	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190181pe/ RP190181*	Maria Teresa Bertilaccio	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190219pe/ RP190219*	Han Liang	The University of Texas M. D. Anderson Cancer Center	S. Dubinett
RP190222pe/ RP190222	Scott Kopetz	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190253pe/ RP190253*	Anil Korkut	The University of Texas M. D. Anderson Cancer Center	G. Powis

Application ID	Applicant/PI	Institution	Conflict Noted
RP190341pe/ RP190341*	Lawrence Kwong	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190352pe	Y. Alan Wang	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190371pe/ RP190371*	Charles Reynolds	Texas Tech University Health Sciences Center	W. Kast
RP190481pe	Justyn Jaworski	The University of Texas at Arlington	S. Dubinett
RP190058pe/ RP190058*	David Fetzer	The University of Texas Southwestern Medical Center	K. Zinn
RP190076pe/ RP190076*	Kenneth Hoyt	The University of Texas at Dallas	J. Basilion;K. Zinn
RP190119pe	Rahul Sheth	The University of Texas M. D. Anderson Cancer Center	W. Cai
RP190164pe/ RP190164*	Anna Sorace	The University of Texas at Austin	K. Zinn
RP190244pe/ RP190244*	Lilie Lin	The University of Texas M. D. Anderson Cancer Center	D. Mankoff
RP190277pe	Kevin Burgess	Texas A&M University	W. Cai
RP190304pe/ RP190304	Baowei Fei	The University of Texas at Dallas	J. Basilion
RP190438pe	Mihaela Stefan	The University of Texas at Dallas	K. Zinn
RP190263	Ricardo Aguiar	The University of Texas Health Science Center at San Antonio	M. McMahon

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards

Academic Research Cycle 19.1

Final Scores for Fully Reviewed Applications

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding.

This comprehensive list of Individual Investigator Research Awards de-identified application scores created for the purpose of this CEO affidavit packet combines the information for all Academic Research review panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. Within each panel, no application with a less favorable score was recommended ahead of an application with a more favorable score.

Application ID	Final Overall Evaluation Score
RP190417*	1.2
RP190451*	1.3
RP190207*	1.9
RP190012*	1.9
RP190043*	2.0
RP190398*	2.0
RP190278*	2.0
RP190019*	2.0
RP190192*	2.1
RP190236*	2.1
RP190301*	2.4
RP190256*	2.4
RP190077*	2.4
RP190295*	2.4
RP190435*	2.4
RP190326*	2.4
RP190218*	2.5
RP190252*	2.5
RP190029*	2.7
RP190131*	2.7
RP190235*	2.8
ia	2.8
RP190454*	2.9
RP190211*	2.9
Aaa**	3.0

* Recommended for award

** Recommended by the SRC and deferred by the Program Integration Committee (PIC)

Application ID	Final Overall Evaluation Score
aab**	3.1
aac**	3.1
ib	3.1
ic	3.2
aad*	3.3
Id	3.3
Ie	3.3
Aae8*	3.4
Aaf**	3.4
If	3.4
Ig	3.5
Ih	3.5
Ii	3.6
Ij	3.6
Ik	3.6
Il	3.6
Im	3.6
In	3.6
Io	3.7
Ip	3.7
Iq	3.7
Ir	3.7
Is	3.7
It	3.7
Iu	3.7
Iv	3.7
Iw	3.7
Ix	3.7
Iy	3.7
Iz	3.7
Ja	3.7
Jb	3.7
Jc	3.7
Jd	3.7
Je	3.7
Jf	3.8
Jg	3.8
Jh	3.8
Ji	3.8
Jj	3.8
Jk	3.9

* Recommended for award
** Recommended by the SRC and deferred by the Program Integration Committee (PIC)

Application ID	Final Overall Evaluation Score
Jl	3.9
Jm	3.9
Jn	3.9
Jo	3.9
Jp	3.9
Jq	3.9
Jr	3.9
Js	3.9
Jt	4.0
Ju	4.0
Jv	4.0
Jw	4.0
Jx	4.0
Jy	4.0
Jz	4.0
Ka	4.0
Kb	4.0
Kc	4.0
Kd	4.0
Ke	4.0
Kf	4.0
Kg	4.0
Kh	4.0
Ki	4.0
Kj	4.0
Kk	4.0
Kl	4.1
Km	4.1
Kn	4.2
Ko	4.2
Kp	4.2
Kq	4.2
Kr	4.3
ks	4.3
Kt	4.3
Ku	4.3
Kv	4.3
Kw	4.3
Kx	4.3
Ky	4.3
Kz	4.3

* Recommended for award
** Recommended by the SRC and deferred by the Program Integration Committee (PIC)

Application ID	Final Overall Evaluation Score
La	4.3
Lb	4.3
Lc	4.3
Ld	4.3
Le	4.3
Lf	4.3
Lg	4.4
Lh	4.4
Li	4.6
Lj	4.6
Lk	4.7
Ll	4.7
Lm	4.7
Ln	4.7
Lo	4.7
Lp	4.7
Lq	4.9
Lr	5.0
Ls	5.0
Lt	5.0
Lu	5.0
Lv	5.0
Lw	5.0
Lx	5.0
Ly	5.0
Lz	5.0
Ma	5.3
Mb	5.3
Mc	5.3
Md	5.5
Me	5.6
Mf	5.7
Mg	5.7
Mh	5.7
Mi	5.7
Mj	6.0
Mk	6.0

* Recommended for award

** Recommended by the SRC and deferred by the Program Integration Committee (PIC)

Individual Investigator Research Awards

Academic Research Cycle 19.1

Final Scores for Preliminary Evaluation

These are the final overall evaluation scores for applications receiving preliminary evaluation that did not move forward to full review. The final overall evaluation score is an average of the preliminary evaluation scores assigned to each application by the primary reviewers.

Application ID	Final Overall Evaluation Score
A	3.7
b	3.7
C	3.7
d	3.7
e	3.7
f	3.7
g	3.7
h	3.7
i	3.7
j	3.7
k	3.7
L	3.7
M	3.7
N	3.7
O	4.0
P	4.0
Q	4.0
R	4.0
S	4.0
T	4.0
U	4.0
V	4.0
W	4.0
X	4.0
Y	4.0
Z	4.0
Aa	4.0
Ab	4.0
Ac	4.0
Ad	4.0
Ae	4.0
Af	4.0

Application ID	Final Overall Evaluation Score
Ag	4.0
Ah	4.0
Ai	4.0
Aj	4.0
Ak	4.0
Al	4.3
Am	4.3
An	4.3
Ao	4.3
Ap	4.3
Aq	4.3
Ar	4.3
As	4.3
At	4.3
Au	4.3
Av	4.3
Aw	4.3
Ax	4.3
Ay	4.3
Az	4.3
Ba	4.3
Bb	4.7
Bc	4.7
Bd	4.7
Be	4.7
Bf	4.7
Bg	4.7
Bh	4.7
Bi	4.7
Bj	4.7
Bk	4.7
Bl	4.7
Bm	4.7
Bn	4.7
Bo	4.7
Bp	4.7
Bq	4.7
Br	4.7
Bs	4.7
Bt	4.7

Application ID	Final Overall Evaluation Score
Bu	4.7
Bv	4.7
Bw	4.7
Bx	4.7
By	4.7
Bz	5.0
Ca	5.0
Cb	5.0
Cc	5.0
Cd	5.0
Ce	5.0
Cf	5.0
Cg	5.0
Ch	5.0
Ci	5.0
Cj	5.0
Ck	5.0
Cl	5.0
Cm	5.0
Cn	5.0
Co	5.0
Cp	5.0
Cq	5.3
Cr	5.3
Cs	5.3
Ct	5.3
Cu	5.3
Cv	5.3
Cw	5.3
Cx	5.3
Cy	5.3
Cz	5.7
Da	5.7
Db	5.7
Dc	5.7
Dd	5.7
De	5.7
Df	6.0
Dg	6.0
Dh	6.0

Application ID	Final Overall Evaluation Score
Di	6.0
Dj	6.0
Dk	6.3
Dl	6.3
dm	7.7

Final Overall Evaluation Scores and Rank Order Scores

LUDWIG
CANCER
RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

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January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Individual Investigator Research Awards (IIRA), the Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), the Individual Investigator Research Awards for Clinical Translation (IIRACT), the Individual Investigator Research Awards for Computational Biology (IIRACB) and the Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on December 5, 2018 to consider the applications recommended by the peer review panels following their meetings that were held October 18, 2018 – October 25, 2018. Please note that RP190135 is included in the list below because it was recommended by the SRC; however, the application was subsequently withdrawn by the applicant.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The total amount for the applications recommended is $50,055,527.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
1	RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252
2	RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000
3	RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577
4	RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892
5	RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473
6	RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433
7	RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000
8	RP190135	IIRACT	**1.9**	Preventing Chemoradiation Bone Marrow Toxicities With FLT PET and SOD Mimics	McGuire, Sarah	The University of Texas Southwestern Medical Center	$2,087,928*
9	RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction in Childhood Cancer Survivors	Noel, Cory V	Baylor College of Medicine	$1,192,412
10	RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000

11	RP190398	IIRA	**2.0**	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566
12	RP190019	IIRA	**2.0**	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000
13	RP190278	IIRA	**2.0**	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000
14	RP190192	IIRA	**2.1**	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000
15	RP190236	IIRA	**2.1**	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397
16	RP190279	IIRAP	**2.2**	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung Carcinogenesis by Omega-3 Fatty Acids	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151
17	RP190160	IIRACT	**2.2**	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000
18	RP190107	IIRACB	**2.3**	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185
19	RP190256	IIRA	**2.4**	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992

20	RP190301	IIRA	2.4	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000
21	RP190077	IIRA	2.4	Molecular Action of Phospho-BRD4–Targeting Compounds in Breast Cancer	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	$864,000**
22	RP190435	IIRA	2.4	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000
23	RP190295	IIRA	2.4	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***
24	RP190326	IIRA	2.4	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000
25	RP190218	IIRA	2.5	Deciphering the Underlying Biology and Translational Relevance of PD-L2	Curran, Michael A	The University of Texas M. D. Anderson Cancer Center	$900,000
26	RP190252	IIRA	2.5	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000
27	RP190210	IIRAP	2.5	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527
28	RP190132	IIRACCA	2.5	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006
29	RP190385	IIRACCA	2.6	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000
30	RP190360	IIRACT	2.6	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991
31	RP190029	IIRA	2.7	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000

32	RP190131	IIRA	2.7	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907
33	RP190235	IIRA	2.8	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747
34	RP190002	IIRACCA	2.8	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218
35	RP190233	IIRACCA	2.8	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000
36	RP190454	IIRA	2.9	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000
37	RP190211	IIRA	2.9	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927
38	RP190251	IIRA	3.0	Defining and Enabling Delivery of microRNA and CRISPR Therapeutics for Hepatocellular Carcinoma (HCC)	Siegwart, Daniel J	The University of Texas Southwestern Medical Center	$900,000
39	RP190414	IIRACCA	3.1	Biochemical and Genetic Interrogation of EWSR1-FLI1 in Ewing Sarcoma	McFadden, David G	The University of Texas Southwestern Medical Center	$1,200,000
40	RP190287	IIRA	3.1	Regulation of CD8 T-Cell Responses in Antitumor Immunity	Sun, Shao-Cong	The University of Texas M. D. Anderson Cancer Center	$900,000
41	RP190421	IIRA	3.1	Structure-Based Drug Design of Inhibitors for a Breast Cancer Signature Kinase	Goldsmith, Elizabeth J	The University of Texas Southwestern Medical Center	$900,000
42	RP190346	IIRACB	3.3	Predicting Drug Response From Genomic Data Using Deep Learning Methods	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$892,157

43	RP190366	IIRA	**3.3**	Characterization and Optimization of Novel Allosteric KRAS Inhibitors	Gorfe, Alemayehu A	The University of Texas Health Science Center at Houston	$897,483
44	RP190208	IIRACB	**3.4**	Dissecting Cellular Heterogeneity of Bulk Tumors for Prediction of Overall Survival and Responsive Patients to Immunotherapy	Wang, Tao	The University of Texas Southwestern Medical Center	$900,000
45	RP190401	IIRACCA	**3.4**	A Mouse Model for Studying DIPG Initiation and Progression in the Pons	Xie, Zhigang	Texas A&M University System Health Science Center	$721,306
46	RP190358	IIRA	**3.4**	The Role of ZMYND8 in Breast Cancer Stem Cells and Tumor Progression	Luo, Weibo	The University of Texas Southwestern Medical Center	$900,000
47	RP190259	IIRA	**3.4**	Role of the N6-Methyladenosine (m6A) Writer METTL3/METTL14 in Cancer	Nam, Yunsun	The University of Texas Southwestern Medical Center	$900,000

*RP190135 – PI withdrew application POST- SRC recommendation and PRE-PIC meeting
**RP190077 reflects budget as reduced by the SRC. SRC recommended the removal of the 3rd aim.
*** RP190295 SRC recommended requiring 10% effort for PI in order to fund.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Individual Investigator Research Awards for Computational Biology

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-19.1-IIRACB

Individual Investigator Research Awards for Computational Biology

Please also refer to the Instructions for Applicants document, which will be posted on March 7, 2018

Application Receipt Opening Date: March 7, 2018

Application Receipt Closing Date: June 6, 2018

FY2019
Fiscal Year Award Period
September 1, 2018–August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 1/11/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.
Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas (liver cancers)

2. RATIONALE

Cancer is a complex disease involving multiple genetic alterations that result in modifications of a large number of cellular processes, both within the cancer cell and in surrounding host tissues. Descriptions of morphological and physiological alterations in cancers using imaging technologies have generated enormous quantities of data, as have analyses of the changes in cancer cells at the molecular and pathway levels. New methods from mathematical and computational biology for cataloging and analyzing such data may accelerate the ability to define cancer prognosis and patient management.

Additionally, it is becoming quite clear that the approach of inhibiting one altered gene or pathway will not be curative for most cancers. Because cancer cell behavior is governed by multiple, nonlinear, interacting pathways, a systems approach is needed. Mathematical models that describe the behavior of cancer cells and how they interact with one another and their environment might be used to predict their responses to combinations and/or sequences of targeted therapies. The use of such computational models could facilitate a deeper understanding of how cancers progress, and/or evolve resistance, as well as accelerate progress in drug development and patient selection for various treatments.

Other work across the spectrum of mathematical and computational biology may address a wide array of problems and challenges in cancer research, including statistical (data analysis), dimensional (visualization), mechanistic (multiscale modeling), and semantic (natural language) research topics.

3. RESEARCH OBJECTIVES

This Request for Applications (RFA) solicits applications for innovative mathematical or computational research projects addressing questions that will advance current knowledge in any aspect of cancer. Applications may address any topic or issue related to cancer causation, identification of populations at risk, prevention, early progression, early detection, treatment, or outcomes. For example, research may address data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging, or genomic, proteomic, and metabolomic databases. It may address descriptive and/or predictive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions. Finally, it may also use artificial intelligence approaches to build new tools for mining cancer research and treatment databases or optimizing treatment strategies. Partnering of computational scientists with cancer biologists or oncologists is highly recommended; a truly interdisciplinary team that addresses models that could become

simulations of structure or pathway functional relationships and changes of these relationships over the disease progression is highly recommended. CPRIT expects the outcomes of activities supported by this mechanism to lead to new insights into cancer biology or clinical outcomes in the long term. CPRIT encourages applications that seek to apply or develop state-of-the-art technologies, tools, and/or resources. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies in computational biology, biostatistics, and/or mathematics.

The subject of applications may include, but is not limited to, the following:

- Analyses of signaling cross-talks among pathways to inform drug inefficacy or drug resistance or reveal novel synergistic drug combinations
- Innovative analyses of various cancer-related databases
- Computational systems biology approaches to cancer drug development
- Identification of subjects at risk of developing cancer
- Image analysis of cells, tissues, organs, and human subjects
- In silico models of cancer development
- Models of tumor-stromal interactions and how they modify progression and treatment
- New methodologies for design of clinical trials
- Modeling of cancer outcomes and economics
- Models of cancer cell signaling systems
- Modeling the aspects of cancer evolution and treatment resistance
- Innovative modeling and quantification of tumor-microenvironment interactions
- Modeling the impact of combinations and sequences of targeted therapy applied to cancer cells

The *degree of relevance* to reducing the burden of cancer is a critical criterion for evaluation of projects for funding by CPRIT (section 9.4.1).

4. FUNDING INFORMATION

Applicants may request a maximum of $300,000 in total costs per year for up to 3 years. Exceptions to these limits may be requested if extremely well justified (see section 8.2.10). Funds may be used for salary and fringe benefits, research supplies, equipment, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law

limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Research Program.
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may not submit applications to this RFA and to RFA-R-19.1-IIRA, RFA-R-19.1-IIRACCA, RFA-R-19.1-IIRACT, or RFA R-19.1-IIRAP. Only 1 IIRA, IIRACT, IIRACB, IIRACCA, or IIRAP application per cycle is allowed. A PI may submit only 1 new or resubmission application under this RFA during this funding cycle. If submitting a renewal application, a PI may submit both a new or resubmission application and a renewal application under this RFA during this funding cycle.
- A PI may be a Co-PI on applications submitted to this RFA and to RFA-R-19.1-IIRACT, RFA-R-19.1-IIRACCA, RFA-R-19.1-IIRA or RFA R-19.1-IIRAP.
- An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants. Recruitment Grants and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers MIRA Project Co-PIs equivalent to a PI. For the purpose of calculating the number of active grants, CPRIT will consider the number of active grants at the time of the award contract effective date (for this cycle expected to be March 1, 2019).
- Applications that address untargeted research, Prevention and Early Detection, Clinical Translation, or Cancers in Children and Adolescents should be submitted under the appropriate targeted RFA.
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included. Collaborators should have specific and well-defined roles.

- Collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would

be considered a resubmission. This policy is in effect for all applications submitted to date. See section 8.2.5.

7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA that is appropriate for the IIRACB mechanism may be submitted under this RFA for a competitive renewal. See section 8.2.6. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See section 9.2.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 7, 2018, and must be submitted by 4 PM central time on June 6, 2018. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk, within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records. Please note that deadline extension requests are very rarely approved.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 5 will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1). Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the layperson's summary. The layperson's summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (2 pages)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh research plan or modify the original research plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches.

8.2.8. Vertebrate Animals and/or Human Subjects (2 pages)

If vertebrate animals will be used, provide a detailed plan of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a detailed plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism. If vertebrate animals and/or human subjects are included in the proposed research, reference biostatistical input for sample selection and evaluation. In addition, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applicants may request a maximum of $300,000 in total costs per year for up to 3 years. Applicants are advised not to interpret the maximum allowable time and funding under this award as a suggestion that they should expand their anticipated work and budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding

indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2019 is $200,000; CPRIT FY 2019 is from September 1, 2018, through August 31, 2019. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. Biographical Sketches (5 pages each)

Applicants are required to provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

8.2.12. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.13. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.14. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

8.3. Formatting Instructions

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English.
- **Document Format:** PDF only.
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Line Spacing:** Single.
- **Page Size:** 8.5 x 11 inches.
- **Margins:** 0.75 inch, all directions.
- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.
- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. Include URLs of publications referenced in the application.

  Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135: 45–67.

- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed in section 9.4. Applicants will be notified of peer review panel assignments prior to the peer review meeting dates. Peer review panel membership can be found on the CPRIT website.

In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC.

The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the

CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Research Officer, and the Commissioner of State Health Services.

The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required experience and creativity to make a significant contribution to the research? Does the applicant investigator demonstrate the required expertise to make a significant contribution in both mathematics and oncology, or are there appropriate collaborators or consultants with expertise in oncology or cancer biology? It is highly encouraged that applicant investigators engage such collaborators. Applicants' credentials will be evaluated in a career stage-specific fashion. Have early-career-stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percent effort) to this project?

Relevance: Does the proposed research address a significant problem related to cancer? Is it likely to make an impact on this disease? This is a critical criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: Is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed?

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release	January 11, 2018

Application

Online application opens	March 7, 2018, 7 AM central time
Application due	June 6, 2018, 4 PM central time
Application review	August–October 2018

Award

Award notification	February 20, 2019
Anticipated start date	March 1, 2019

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In

addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. A grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the 5% indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time.

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Academic Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-1 Peer Review Meeting
(19.1_ACR_BCR-1)
Observation Report

Report No.	2018-10-19 19.1_ACR_BCR-1
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-1_Peer Review Meeting (19.1_ACR_BCR-1)
Panel Date:	10-19-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-1_Peer Review (19.1_ACR_BCR-1) meeting. The meeting was chaired by Thomas Curran and conducted via in-person in Dallas, Texas on October 19, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and eighteen (18) were not discussed
- Panelists: One (1) panel chair and fourteen (14) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

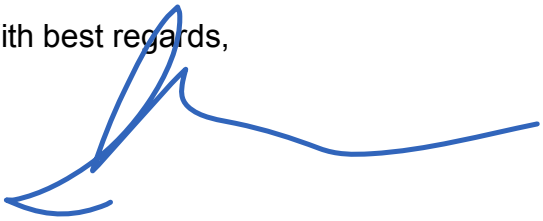
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-2 Peer Review Meeting
(19.1_ACR_BCR-2)
Observation Report

Report No.	2018-10-23 19.1_ACR_BCR-2
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-2_Peer Review Meeting (19.1_ACR_BCR-2)
Panel Date:	10-23-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-2_Peer Review (19.1_ACR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via in-person in Dallas, Texas on October 23, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and fifteen (15) were not discussed
- Panelists: One (1) panel chair and seventeen (17) expert reviewers and one (1) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and two (2) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

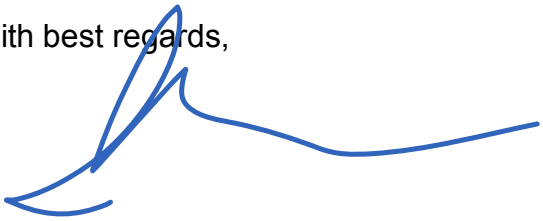
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Biology Peer Review Meeting (19.1 ACR CB)
Observation Report

Report No.	2018-10-22 19.1_ACR_CB
Program Name:	Academic Research
Panel Name:	Cancer Biology Peer Review Meeting (19.1_ACR_CB)
Panel Date:	10/22/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Biology Peer Review (19.1_ACR_CB) meeting. The meeting was chaired by Peter Jones and conducted via in-person in Dallas, Texas on October 22, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and nineteen (19) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were five (5) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

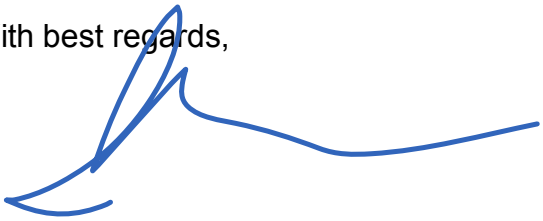
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Prevention Research Peer Review Meeting
(19.1_ACR_CPR)
Observation Report

Report No.	2018-10-24 19.1_ACR_CPR
Program Name:	Academic Research
Panel Name:	Cancer Prevention Research Peer Review Meeting (19.1_ACR_CPR)
Panel Date:	10/24/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Prevention Research Peer Review (19.1_ACR_CPR) meeting. The meeting was chaired by Thomas Sellars and conducted via in-person in Dallas, Texas on October 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eighteen (18) applications were discussed and fourteen (14) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eighteen (18) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

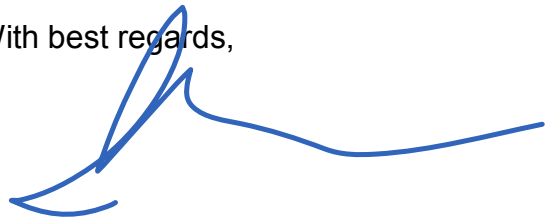
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Clinical/Translational Cancer Research Peer Review Meeting
(19.1 ACR C/TCR)
Observation Report

Report No.	2018-10-25 19.1_ACR_C/TCR
Program Name:	Academic Research
Panel Name:	Clinical/Translational Cancer Research Peer Review Meeting (19.1_ACR_C/TCR)
Panel Date:	10/25/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Clinical/Translational Cancer Research Peer Review (19.1_ACR_C/TCR) meeting. The meeting was chaired by Margaret Tempero and Richard O'Reilly and conducted via in-person in Dallas, Texas on October 25, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and twenty-one (21) were not discussed
- Panelists: Two (2) panel chairs, twenty-three (23) expert reviewers and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were ten (10) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

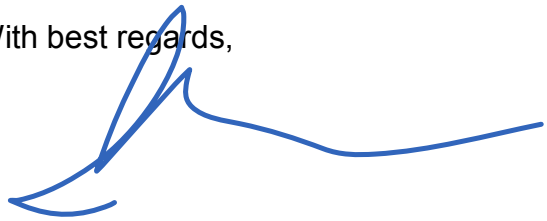
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Imaging Technology and Informatics Review Meeting
(19.1_ACR_ITI)
Observation Report

Report No.	2018-10-18 19.1_ACR_ITI
Program Name:	Academic Research
Panel Name:	Imaging Technology and Informatics Review Meeting (19.1_ACR_ITI)
Panel Date:	10/18/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Imaging Technology and Informatics Review Meeting (19.1_ITI) meeting. The meeting was chaired by Sanjiv Sam Gambhir and conducted via in-person in Dallas, Texas on October 18, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seventeen (17) applications were discussed and twenty-one (21) were not discussed
- Panelists: One (1) panel chair and twenty (20) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

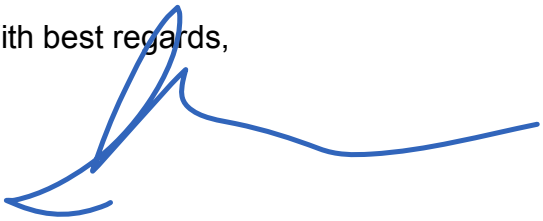
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)

19.1 Scientific Review Council Meeting (19.1 SRC) Observation Report

Report No. 2018-12-05 19.1_SRC
Program Name: Academic Research
Panel Name: 19.1 Scientific Review Council Meeting (19.1_SRC)
Panel Date: 12/05/2018
Report Date: 12/05/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Scientific Review Council Meeting (19.1_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via or teleconference on December 5, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Forty-seven (47) applications were discussed and zero (0) were not discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

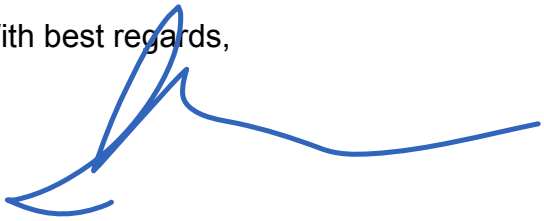
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Academic Research 19.1 Applications
(Academic Research Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 19.1 include *Individual Investigator Research Awards, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Clinical Translation, Individual Investigator Research Awards for Computational Biology,* and *Individual Investigator Research Awards for Prevention and Early Detection.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP190414pe/ RP190414	David McFadden	The University of Texas Southwestern Medical Center	M. McMahon
RP190077pe/ RP190077	Cheng-Ming Chiang	The University of Texas Southwestern Medical Center	T. Kodadek
RP190301pe	Ilya Finkelstein	The University of Texas at Austin	A. Tomkinson;C. Prives;W. Chazin
RP190301	Ilya Finkelstein	The University of Texas at Austin	J. Manley
RP190421pe/ RP190421	Elizabeth Goldsmith	The University of Texas Southwestern Medical Center	A. Tomkinson;T. Kodadek
RP190398pe	Rachel Schiff	Baylor College of Medicine	G. Greene
RP190398	Rachel Schiff	Baylor College of Medicine	A. Tonachel;G. Greene
RP190210pe/ RP190210	Robert Volk	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon

Application ID	Applicant/PI	Institution	Conflict Noted
RP190326pe/ RP190326	Roza Nurieva	The University of Texas M. D. Anderson Cancer Center	S. Dubinett;V. Engelhard
RP190019pe/ RP190019	Eva Sevick	The University of Texas Health Science Center at Houston	A. Wu
RP190211pe/ RP190211	Mark Pagel	The University of Texas M. D. Anderson Cancer Center	J. Basilion
Applications not considered by the PIC or Oversight Committee			
RP190464pe/ RP190464	Everett Stone	The University of Texas at Austin	G. Prendergast
RP190087pe/ RP190087*	John Tainer	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson;W. Chazin
RP190203pe/ RP190203*	Pawel Mazur	The University of Texas M. D. Anderson Cancer Center	N. Bardeesy
RP190314pe	Jason Huse	The University of Texas M. D. Anderson Cancer Center	J. Petrini
RP190332pe/ RP190332*	Steven Millward	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson
RP190078pe/ RP190078*	Ralf Krahe	The University of Texas M. D. Anderson Cancer Center	J. Issa
RP190245pe	Yunfei Wen	The University of Texas M. D. Anderson Cancer Center	M. Hollingsworth
RP190356pe/ RP190356*	Jung-whan Kim	The University of Texas at Dallas	M. Hollingsworth
RP190458pe/ RP190458	Robert Chapkin	Texas AgriLife Research	E. Fearon
RP190039pe/ RP190039*	Divya Patel	The University of Texas Health Center at Tyler	T. Brandon
RP190044pe/ RP190044	Jason Robinson	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190054pe/ RP190054	Sheng Pan	The University of Texas Health Science Center at Houston	C. Li;G. Petersen;W. Barlow

Application ID	Applicant/PI	Institution	Conflict Noted
RP190062pe/ RP190062	Wenyi Wang	The University of Texas M. D. Anderson Cancer Center	L. Mucci
RP190068pe/ RP190068*	Jian Gu	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190139pe/ RP190139	Alexander Prokhorov	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190232pe/ RP190232*	Manal Hassan	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190281pe	Olena Weaver	The University of Texas M. D. Anderson Cancer Center	C. Li
RP190321pe/ RP190321*	Lindsay Cowell	The University of Texas Southwestern Medical Center	C. Li;W. Barlow
RP190357pe/ RP190357	Subrata Sen	The University of Texas M. D. Anderson Cancer Center	G. Petersen;W. Barlow
RP190479pe/ RP190479*	Xuexia Wang	University of North Texas	L. Kushi
RP190016pe	Damith Udugamasooriya	University of Houston	S. Dubinett
RP190148pe/ RP190148*	Chun Li	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190166pe/ RP190166*	Khandan Keyomarsi	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190181pe/ RP190181*	Maria Teresa Bertilaccio	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190219pe/ RP190219*	Han Liang	The University of Texas M. D. Anderson Cancer Center	S. Dubinett
RP190222pe/ RP190222	Scott Kopetz	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190253pe/ RP190253*	Anil Korkut	The University of Texas M. D. Anderson Cancer Center	G. Powis

Application ID	Applicant/PI	Institution	Conflict Noted
RP190341pe/ RP190341*	Lawrence Kwong	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190352pe	Y. Alan Wang	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190371pe/ RP190371*	Charles Reynolds	Texas Tech University Health Sciences Center	W. Kast
RP190481pe	Justyn Jaworski	The University of Texas at Arlington	S. Dubinett
RP190058pe/ RP190058*	David Fetzer	The University of Texas Southwestern Medical Center	K. Zinn
RP190076pe/ RP190076*	Kenneth Hoyt	The University of Texas at Dallas	J. Basilion;K. Zinn
RP190119pe	Rahul Sheth	The University of Texas M. D. Anderson Cancer Center	W. Cai
RP190164pe/ RP190164*	Anna Sorace	The University of Texas at Austin	K. Zinn
RP190244pe/ RP190244*	Lilie Lin	The University of Texas M. D. Anderson Cancer Center	D. Mankoff
RP190277pe	Kevin Burgess	Texas A&M University	W. Cai
RP190304pe/ RP190304	Baowei Fei	The University of Texas at Dallas	J. Basilion
RP190438pe	Mihaela Stefan	The University of Texas at Dallas	K. Zinn
RP190263	Ricardo Aguiar	The University of Texas Health Science Center at San Antonio	M. McMahon

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards for Computational Biology

Academic Research Cycle 19.1

Final Scores for Fully Reviewed Applications

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding.

This comprehensive list of Individual Investigator Research Awards de-identified application scores created for the purpose of this CEO affidavit packet combines the information for all Academic Research review panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. Within each panel, no application with a less favorable score was recommended ahead of an application with a more favorable score.

Application ID	Final Overall Evaluation Score
RP190107*	2.3
Bba**	3.3
Oa	3.3
BBB**	3.4
Ob	3.7
oc	3.7
Od	3.8
Oe	3.9
Of	4.0
Og	4.3
Oh	5.0
Oi	5.7

* Recommended for award

** Recommended for award by the SRC and deferred by the Program Integration Committee (PIC)

Individual Investigator Research Awards for Computational Biology

Academic Research Cycle 19.1

Final Scores for Preliminary Evaluation

These are the final overall evaluation scores for applications receiving preliminary evaluation that did not move forward to full review. The final overall evaluation score is an average of the preliminary evaluation scores assigned to each application by the primary reviewers.

Application ID	Final Overall Evaluation Score
Ea	4.0
Eb	4.0
Ec	4.0
Ed	4.3
Ee	4.3
Ef	4.7
Eg	4.7
Eh	5.0
Ei	5.0
Ej	5.5
Ek	5.7
El	5.7
Em	6.0

Final Overall Evaluation Scores and Rank Order Scores

LUDWIG
CANCER
RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Individual Investigator Research Awards (IIRA), the Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), the Individual Investigator Research Awards for Clinical Translation (IIRACT), the Individual Investigator Research Awards for Computational Biology (IIRACB) and the Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on December 5, 2018 to consider the applications recommended by the peer review panels following their meetings that were held October 18, 2018 – October 25, 2018. Please note that RP190135 is included in the list below because it was recommended by the SRC; however, the application was subsequently withdrawn by the applicant.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The total amount for the applications recommended is $50,055,527.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
1	RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252
2	RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000
3	RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577
4	RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892
5	RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473
6	RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433
7	RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000
8	RP190135	IIRACT	**1.9**	Preventing Chemoradiation Bone Marrow Toxicities With FLT PET and SOD Mimics	McGuire, Sarah	The University of Texas Southwestern Medical Center	$2,087,928*
9	RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction in Childhood Cancer Survivors	Noel, Cory V	Baylor College of Medicine	$1,192,412
10	RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000

11	RP190398	IIRA	**2.0**	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566
12	RP190019	IIRA	**2.0**	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000
13	RP190278	IIRA	**2.0**	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000
14	RP190192	IIRA	**2.1**	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000
15	RP190236	IIRA	**2.1**	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397
16	RP190279	IIRAP	**2.2**	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung Carcinogenesis by Omega-3 Fatty Acids	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151
17	RP190160	IIRACT	**2.2**	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000
18	RP190107	IIRACB	**2.3**	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185
19	RP190256	IIRA	**2.4**	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992

20	RP190301	IIRA	2.4	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000
21	RP190077	IIRA	2.4	Molecular Action of Phospho-BRD4–Targeting Compounds in Breast Cancer	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	$864,000**
22	RP190435	IIRA	2.4	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000
23	RP190295	IIRA	2.4	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***
24	RP190326	IIRA	2.4	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000
25	RP190218	IIRA	2.5	Deciphering the Underlying Biology and Translational Relevance of PD-L2	Curran, Michael A	The University of Texas M. D. Anderson Cancer Center	$900,000
26	RP190252	IIRA	2.5	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000
27	RP190210	IIRAP	2.5	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527
28	RP190132	IIRACCA	2.5	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006
29	RP190385	IIRACCA	2.6	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000
30	RP190360	IIRACT	2.6	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991
31	RP190029	IIRA	2.7	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000

32	RP190131	IIRA	2.7	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907
33	RP190235	IIRA	2.8	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747
34	RP190002	IIRACCA	2.8	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218
35	RP190233	IIRACCA	2.8	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000
36	RP190454	IIRA	2.9	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000
37	RP190211	IIRA	2.9	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927
38	RP190251	IIRA	3.0	Defining and Enabling Delivery of microRNA and CRISPR Therapeutics for Hepatocellular Carcinoma (HCC)	Siegwart, Daniel J	The University of Texas Southwestern Medical Center	$900,000
39	RP190414	IIRACCA	3.1	Biochemical and Genetic Interrogation of EWSR1-FLI1 in Ewing Sarcoma	McFadden, David G	The University of Texas Southwestern Medical Center	$1,200,000
40	RP190287	IIRA	3.1	Regulation of CD8 T-Cell Responses in Antitumor Immunity	Sun, Shao-Cong	The University of Texas M. D. Anderson Cancer Center	$900,000
41	RP190421	IIRA	3.1	Structure-Based Drug Design of Inhibitors for a Breast Cancer Signature Kinase	Goldsmith, Elizabeth J	The University of Texas Southwestern Medical Center	$900,000
42	RP190346	IIRACB	3.3	Predicting Drug Response From Genomic Data Using Deep Learning Methods	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$892,157

43	RP190366	IIRA	**3.3**	Characterization and Optimization of Novel Allosteric KRAS Inhibitors	Gorfe, Alemayehu A	The University of Texas Health Science Center at Houston	$897,483
44	RP190208	IIRACB	**3.4**	Dissecting Cellular Heterogeneity of Bulk Tumors for Prediction of Overall Survival and Responsive Patients to Immunotherapy	Wang, Tao	The University of Texas Southwestern Medical Center	$900,000
45	RP190401	IIRACCA	**3.4**	A Mouse Model for Studying DIPG Initiation and Progression in the Pons	Xie, Zhigang	Texas A&M University System Health Science Center	$721,306
46	RP190358	IIRA	**3.4**	The Role of ZMYND8 in Breast Cancer Stem Cells and Tumor Progression	Luo, Weibo	The University of Texas Southwestern Medical Center	$900,000
47	RP190259	IIRA	**3.4**	Role of the N6-Methyladenosine (m6A) Writer METTL3/METTL14 in Cancer	Nam, Yunsun	The University of Texas Southwestern Medical Center	$900,000

*RP190135 – PI withdrew application POST- SRC recommendation and PRE-PIC meeting
**RP190077 reflects budget as reduced by the SRC. SRC recommended the removal of the 3rd aim.
*** RP190295 SRC recommended requiring 10% effort for PI in order to fund.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Individual Investigator Research Awards for Cancer in Children and Adolescents

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-19.1-IIRACCA

Individual Investigator Research Awards for Cancer in Children and Adolescents

Please also refer to the Instructions for Applicants document, which will be posted on March 7, 2018

Application Receipt Opening Date: March 7, 2018

Application Receipt Closing Date: June 6, 2018

FY 2019
Fiscal Year Award Period
September 1, 2018–August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 1/11/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas (liver cancers)

2. RATIONALE

In recent decades, great strides have been made in reducing mortality from childhood cancers. Most of these gains have been realized in childhood leukemia and lymphoma. However, improvements in survival have been less robust in other types of childhood cancers, which make up more than 40% of total cancer cases in children and adolescents aged 0 to 19 years. Furthermore, the overall incidence of pediatric cancer has increased at an annual rate of 0.6% since 1975, with most of the increases being seen in acute lymphocytic leukemia, brain and central nervous system tumors, non-Hodgkin's lymphoma, and testicular germ cell tumors. Reasons for increases in these tumor types are unknown, indicating that information on the etiology of these cancers is urgently needed. Because of the high rates of survival for certain childhood and adolescent cancers, there are increasing numbers of survivors of such cancers living today. These individuals have a high rate of late effects from the cancer or its treatment, including the occurrence of additional cancers. Clearly, more effective, less toxic treatments are needed for these diseases. However, few new therapies have been developed in recent years. Several reasons account for the paucity of new treatments, including the lack of interest on the part of pharmaceutical companies in developing treatments for cancers that account for only 1% of all cancer cases and the difficulty of collecting sufficient numbers of tumors for laboratory studies.

Because cancers in children and adolescents differ from those in adults with regard to genetic alterations and biological behavior, application of adult therapies to these cancers may not be successful. Therefore, this area of investigation represents an opportunity for CPRIT to deploy funding in an area of critical need that is not heavily represented in other funding portfolios.

3. RESEARCH OBJECTIVES

This Request for Applications (RFA) solicits applications from individual investigators for innovative research projects addressing questions that will advance current knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Applications may address any topic related to these areas as well as projects dealing with the causes or amelioration of late effects of cancer treatment. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Applications that seek to apply or develop state-of-the-art approaches, technologies, tools, treatments, and/or resources are encouraged, particularly those with potential for

commercialization. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies.

The subject of applications may include, but is not limited to, the following:

- Causes of cancer in children and adolescents, including genetic factors or prenatal exposure to environmental agents;
- Identification of risk factors for cancer development;
- New methods for diagnosing cancers in children and/or adolescents;
- Development of new therapies, including targeted therapies, immunotherapies, and new drugs;
- Identification of patients at risk of developing late effects of cancer treatment;
- Improvements in quality of life for survivors of childhood and adolescent cancers.

The *degree of relevance* to reducing the burden of cancer in these populations is a critical criterion for evaluation of projects for funding by CPRIT.

4. FUNDING INFORMATION

Applicants may request a maximum of $300,000 per year for a period of up to 4 years. Applicants that plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs per year for up to 4 years. Note that an individual detailed budget for conducting a clinical trial is required. Exceptions to these limits may be requested if extremely well justified. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Research Program.

- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may not submit applications to this RFA and to RFA-R-19.1-IIRA, RFA-R-19.1-IIRACB, RFA-R-19.1-IIRACT, or RFA R-19.1-IIRAP. Only 1 IIRA, IIRACT, IIRACB, IIRACCA, or IIRAP application per cycle is allowed. A PI may submit only 1 new or resubmission application under this RFA during this funding cycle. If submitting a renewal application, a PI may submit both a new or resubmission application and a renewal application under this RFA during this funding cycle.
- A PI may be a Co-PI on applications submitted to this RFA and to RFA-R-19.1-IIRACB, RFA-R-19.1-IIRACT, RFA R-19.1-IIRA, or RFA R-19.1-IIRAP.
- An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants. Recruitment Grants and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers MIRA Project Co-PIs equivalent to a PI. For the purpose of calculating the number of active grants, CPRIT will consider the number of active grants at the time of the award contract effective date (for this cycle expected to be March 1, 2019).
- Applications that address untargeted research, Prevention and Early Detection, Clinical Translation, or Computational Biology should be submitted under the appropriate targeted RFA.
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included.
- Collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the

grant applicant's organization or institution is related to a CPRIT Oversight Committee member.

- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. This policy is in effect for all applications submitted to date. See section 8.2.5.

7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA that is appropriate for the IIRACCA mechanism may be submitted under this RFA for a competitive renewal. See section 8.2.6. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See section 9.2.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 7, 2018, and must be submitted by 4 PM central time on June 6, 2018. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk, within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records. Please note that deadline extension requests are very rarely approved.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 5 will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. **Based on this statement (and the Budget and Justification and Biographical**

Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1). Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the layperson's summary. The layperson's summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (2 Pages)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh research plan or modify the original research plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

8.2.8. Vertebrate Animals and/or Human Subjects (2 pages)

If vertebrate animals will be used, provide a detailed plan of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a detailed plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism. If vertebrate animals and/or human subjects are included in the proposed research, reference biostatistical input for sample selection and evaluation. In addition,

certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, costs associated with the conduct of a clinical trial, animal care costs, and other expenses. Do not exceed $300,000 per year for a period of up to 4 years. Applicants who plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs per year for up to 4 years. While there will be 1 budget for the entire project, an individual budget and budget justification for the conduct of a clinical trial must be included. The justification should include the statistical considerations that led to the clinical trial design, accrual milestones, and validation of biomarkers. Applicants are advised not to interpret the maximum allowable time and funding under this award as a suggestion that they should expand their anticipated work and budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2019 is $200,000; CPRIT FY 2019 is from September 1, 2018, through August 31, 2019. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. Biographical Sketches (5 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

8.2.12. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.13. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.14. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

8.3. Formatting Instructions

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English.
- **Document Format:** PDF only.
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Line Spacing:** Single.
- **Page Size:** 8.5 x 11 inches.
- **Margins:** 0.75 inch, all directions.
- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.
- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. Include URLs of publications referenced in the application.

  Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135: 45–67.

- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria

listed in section 9.4. Applicants will be notified of peer review panel assignments prior to the peer review meeting dates. Peer review panel membership can be found on the CPRIT website. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC.

The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an

Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Research Officer, and the Commissioner of State Health Services.

The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and expertise to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage–specific fashion. Have early-career-stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percent effort) to this project?

Relevance: Does the proposed research address cancer in children or adolescents? Is it likely to make an impact on these diseases? This is a critical criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: Is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed?

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release	January 11, 2018

Application

Online application opens	March 7, 2018, 7 AM central time
Application due	June 6, 2018, 4 PM central time
Application review	August–October 2018

Award

Award notification	February 20, 2019
Anticipated start date	March 1, 2019

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports.

Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. A grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the 5% indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time.

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Academic Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-1 Peer Review Meeting
(19.1_ACR_BCR-1)
Observation Report

Report No.	2018-10-19 19.1_ACR_BCR-1
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-1_Peer Review Meeting (19.1_ACR_BCR-1)
Panel Date:	10-19-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-1_Peer Review (19.1_ACR_BCR-1) meeting. The meeting was chaired by Thomas Curran and conducted via in-person in Dallas, Texas on October 19, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and eighteen (18) were not discussed
- Panelists: One (1) panel chair and fourteen (14) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

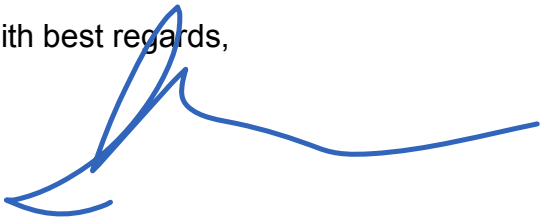
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-2 Peer Review Meeting
(19.1_ACR_BCR-2)
Observation Report

Report No.	2018-10-23 19.1_ACR_BCR-2
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-2_Peer Review Meeting (19.1_ACR_BCR-2)
Panel Date:	10-23-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-2_Peer Review (19.1_ACR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via in-person in Dallas, Texas on October 23, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and fifteen (15) were not discussed
- Panelists: One (1) panel chair and seventeen (17) expert reviewers and one (1) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and two (2) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

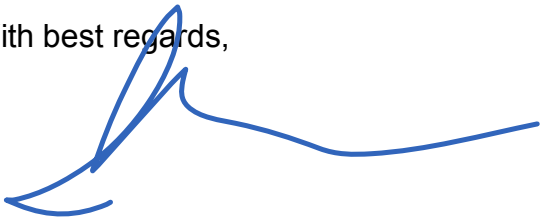
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Biology Peer Review Meeting (19.1 ACR CB)
Observation Report

Report No.	2018-10-22 19.1_ACR_CB
Program Name:	Academic Research
Panel Name:	Cancer Biology Peer Review Meeting (19.1_ACR_CB)
Panel Date:	10/22/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Biology Peer Review (19.1_ACR_CB) meeting. The meeting was chaired by Peter Jones and conducted via in-person in Dallas, Texas on October 22, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and nineteen (19) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were five (5) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

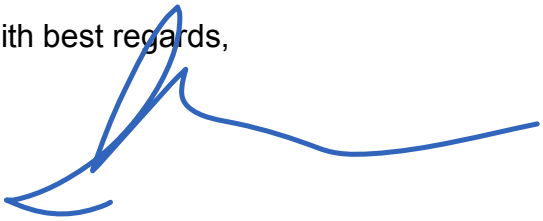
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Prevention Research Peer Review Meeting
(19.1_ACR_CPR)
Observation Report

Report No.	2018-10-24 19.1_ACR_CPR
Program Name:	Academic Research
Panel Name:	Cancer Prevention Research Peer Review Meeting (19.1_ACR_CPR)
Panel Date:	10/24/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Prevention Research Peer Review (19.1_ACR_CPR) meeting. The meeting was chaired by Thomas Sellars and conducted via in-person in Dallas, Texas on October 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eighteen (18) applications were discussed and fourteen (14) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eighteen (18) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

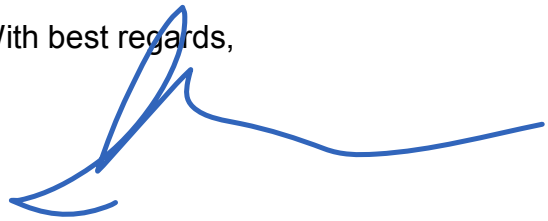
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Clinical/Translational Cancer Research Peer Review Meeting
(19.1 ACR C/TCR)
Observation Report

Report No.	2018-10-25 19.1_ACR_C/TCR
Program Name:	Academic Research
Panel Name:	Clinical/Translational Cancer Research Peer Review Meeting (19.1_ACR_C/TCR)
Panel Date:	10/25/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Clinical/Translational Cancer Research Peer Review (19.1_ACR_C/TCR) meeting. The meeting was chaired by Margaret Tempero and Richard O'Reilly and conducted via in-person in Dallas, Texas on October 25, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and twenty-one (21) were not discussed
- Panelists: Two (2) panel chairs, twenty-three (23) expert reviewers and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were ten (10) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

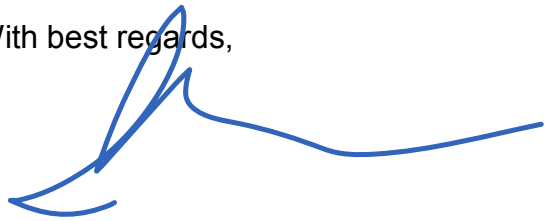
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Imaging Technology and Informatics Review Meeting
(19.1_ACR_ITI)
Observation Report

Report No.	2018-10-18 19.1_ACR_ITI
Program Name:	Academic Research
Panel Name:	Imaging Technology and Informatics Review Meeting (19.1_ACR_ITI)
Panel Date:	10/18/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Imaging Technology and Informatics Review Meeting (19.1_ITI) meeting. The meeting was chaired by Sanjiv Sam Gambhir and conducted via in-person in Dallas, Texas on October 18, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seventeen (17) applications were discussed and twenty-one (21) were not discussed
- Panelists: One (1) panel chair and twenty (20) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

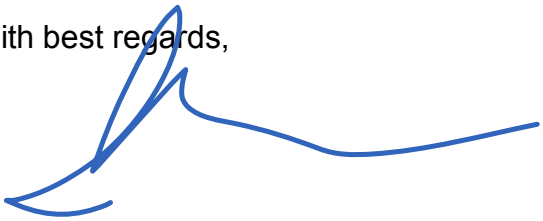
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
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cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)

19.1 Scientific Review Council Meeting (19.1 SRC) Observation Report

Report No. 2018-12-05 19.1_SRC
Program Name: Academic Research
Panel Name: 19.1 Scientific Review Council Meeting (19.1_SRC)
Panel Date: 12/05/2018
Report Date: 12/05/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Scientific Review Council Meeting (19.1_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via or teleconference on December 5, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Forty-seven (47) applications were discussed and zero (0) were not discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

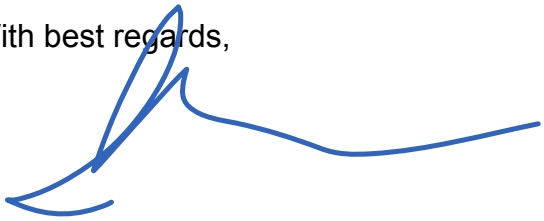
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Academic Research 19.1 Applications
(Academic Research Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 19.1 include *Individual Investigator Research Awards, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Clinical Translation, Individual Investigator Research Awards for Computational Biology,* and *Individual Investigator Research Awards for Prevention and Early Detection.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP190414pe/ RP190414	David McFadden	The University of Texas Southwestern Medical Center	M. McMahon
RP190077pe/ RP190077	Cheng-Ming Chiang	The University of Texas Southwestern Medical Center	T. Kodadek
RP190301pe	Ilya Finkelstein	The University of Texas at Austin	A. Tomkinson;C. Prives;W. Chazin
RP190301	Ilya Finkelstein	The University of Texas at Austin	J. Manley
RP190421pe/ RP190421	Elizabeth Goldsmith	The University of Texas Southwestern Medical Center	A. Tomkinson;T. Kodadek
RP190398pe	Rachel Schiff	Baylor College of Medicine	G. Greene
RP190398	Rachel Schiff	Baylor College of Medicine	A. Tonachel;G. Greene
RP190210pe/ RP190210	Robert Volk	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon

Application ID	Applicant/PI	Institution	Conflict Noted
RP190326pe/ RP190326	Roza Nurieva	The University of Texas M. D. Anderson Cancer Center	S. Dubinett;V. Engelhard
RP190019pe/ RP190019	Eva Sevick	The University of Texas Health Science Center at Houston	A. Wu
RP190211pe/ RP190211	Mark Pagel	The University of Texas M. D. Anderson Cancer Center	J. Basilion
Applications not considered by the PIC or Oversight Committee			
RP190464pe/ RP190464	Everett Stone	The University of Texas at Austin	G. Prendergast
RP190087pe/ RP190087*	John Tainer	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson;W. Chazin
RP190203pe/ RP190203*	Pawel Mazur	The University of Texas M. D. Anderson Cancer Center	N. Bardeesy
RP190314pe	Jason Huse	The University of Texas M. D. Anderson Cancer Center	J. Petrini
RP190332pe/ RP190332*	Steven Millward	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson
RP190078pe/ RP190078*	Ralf Krahe	The University of Texas M. D. Anderson Cancer Center	J. Issa
RP190245pe	Yunfei Wen	The University of Texas M. D. Anderson Cancer Center	M. Hollingsworth
RP190356pe/ RP190356*	Jung-whan Kim	The University of Texas at Dallas	M. Hollingsworth
RP190458pe/ RP190458	Robert Chapkin	Texas AgriLife Research	E. Fearon
RP190039pe/ RP190039*	Divya Patel	The University of Texas Health Center at Tyler	T. Brandon
RP190044pe/ RP190044	Jason Robinson	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190054pe/ RP190054	Sheng Pan	The University of Texas Health Science Center at Houston	C. Li;G. Petersen;W. Barlow

Application ID	Applicant/PI	Institution	Conflict Noted
RP190062pe/ RP190062	Wenyi Wang	The University of Texas M. D. Anderson Cancer Center	L. Mucci
RP190068pe/ RP190068*	Jian Gu	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190139pe/ RP190139	Alexander Prokhorov	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190232pe/ RP190232*	Manal Hassan	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190281pe	Olena Weaver	The University of Texas M. D. Anderson Cancer Center	C. Li
RP190321pe/ RP190321*	Lindsay Cowell	The University of Texas Southwestern Medical Center	C. Li;W. Barlow
RP190357pe/ RP190357	Subrata Sen	The University of Texas M. D. Anderson Cancer Center	G. Petersen;W. Barlow
RP190479pe/ RP190479*	Xuexia Wang	University of North Texas	L. Kushi
RP190016pe	Damith Udugamasooriya	University of Houston	S. Dubinett
RP190148pe/ RP190148*	Chun Li	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190166pe/ RP190166*	Khandan Keyomarsi	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190181pe/ RP190181*	Maria Teresa Bertilaccio	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190219pe/ RP190219*	Han Liang	The University of Texas M. D. Anderson Cancer Center	S. Dubinett
RP190222pe/ RP190222	Scott Kopetz	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190253pe/ RP190253*	Anil Korkut	The University of Texas M. D. Anderson Cancer Center	G. Powis

Application ID	Applicant/PI	Institution	Conflict Noted
RP190341pe/ RP190341*	Lawrence Kwong	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190352pe	Y. Alan Wang	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190371pe/ RP190371*	Charles Reynolds	Texas Tech University Health Sciences Center	W. Kast
RP190481pe	Justyn Jaworski	The University of Texas at Arlington	S. Dubinett
RP190058pe/ RP190058*	David Fetzer	The University of Texas Southwestern Medical Center	K. Zinn
RP190076pe/ RP190076*	Kenneth Hoyt	The University of Texas at Dallas	J. Basilion;K. Zinn
RP190119pe	Rahul Sheth	The University of Texas M. D. Anderson Cancer Center	W. Cai
RP190164pe/ RP190164*	Anna Sorace	The University of Texas at Austin	K. Zinn
RP190244pe/ RP190244*	Lilie Lin	The University of Texas M. D. Anderson Cancer Center	D. Mankoff
RP190277pe	Kevin Burgess	Texas A&M University	W. Cai
RP190304pe/ RP190304	Baowei Fei	The University of Texas at Dallas	J. Basilion
RP190438pe	Mihaela Stefan	The University of Texas at Dallas	K. Zinn
RP190263	Ricardo Aguiar	The University of Texas Health Science Center at San Antonio	M. McMahon

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards for Cancer in Children and Adolescents

Academic Research Cycle 19.1

Final Scores for Fully Reviewed Applications

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding.

This comprehensive list of Individual Investigator Research Awards de-identified application scores created for the purpose of this CEO affidavit packet combines the information for all Academic Research review panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. Within each panel, no application with a less favorable score was recommended ahead of an application with a more favorable score.

Application ID	Final Overall Evaluation Score
RP190400*	1.9
RP190132*	2.5
RP190385*	2.6
RP190233*	2.8
RP190002*	2.8
Cca**	3.1
Ccb**	3.4
oa	3.4
Ob	3.6
Oc	3.7
Od	3.7
Oe	3.7
Of	3.8
Og	4.0
Oh	4.0
Oi	4.0
Oj	4.0
Ok	4.0
Ol	4.3
Om	4.3
On	4.3
Oo	4.7
Op	4.9

* Recommended for award

** Recommended for award by the SRC and deferred by the Program Integration Committee (PIC)

Application ID	Final Overall Evaluation Score
Oq	5.0

* Recommended for award

** Recommended for award by the SRC and deferred by the Program Integration Committee (PIC)

Individual Investigator Research Awards for Cancer in Children and Adolescents

Academic Research Cycle 19.1

Final Scores for Preliminary Evaluation

These are the final overall evaluation scores for applications receiving preliminary evaluation that did not move forward to full review. The final overall evaluation score is an average of the preliminary evaluation scores assigned to each application by the primary reviewers.

Application ID	Final Overall Evaluation Score
Fa	3.7
Fb	4.0
Fc	4.0
Fd	4.3
Fe	4.3
Ff	4.3
Fg	4.7
Fh	4.7
Fi	5.0
Fj	5.0
Fk	5.0

Final Overall Evaluation Scores and Rank Order Scores

LUDWIG
CANCER
RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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T 858 534 7804
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January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Individual Investigator Research Awards (IIRA), the Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), the Individual Investigator Research Awards for Clinical Translation (IIRACT), the Individual Investigator Research Awards for Computational Biology (IIRACB) and the Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on December 5, 2018 to consider the applications recommended by the peer review panels following their meetings that were held October 18, 2018 – October 25, 2018. Please note that RP190135 is included in the list below because it was recommended by the SRC; however, the application was subsequently withdrawn by the applicant.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The total amount for the applications recommended is $50,055,527.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
1	RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252
2	RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000
3	RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577
4	RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892
5	RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473
6	RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433
7	RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000
8	RP190135	IIRACT	**1.9**	Preventing Chemoradiation Bone Marrow Toxicities With FLT PET and SOD Mimics	McGuire, Sarah	The University of Texas Southwestern Medical Center	$2,087,928*
9	RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction in Childhood Cancer Survivors	Noel, Cory V	Baylor College of Medicine	$1,192,412
10	RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000

11	RP190398	IIRA	**2.0**	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566
12	RP190019	IIRA	**2.0**	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000
13	RP190278	IIRA	**2.0**	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000
14	RP190192	IIRA	**2.1**	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000
15	RP190236	IIRA	**2.1**	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397
16	RP190279	IIRAP	**2.2**	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung Carcinogenesis by Omega-3 Fatty Acids	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151
17	RP190160	IIRACT	**2.2**	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000
18	RP190107	IIRACB	**2.3**	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185
19	RP190256	IIRA	**2.4**	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992

20	RP190301	IIRA	2.4	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000
21	RP190077	IIRA	2.4	Molecular Action of Phospho-BRD4–Targeting Compounds in Breast Cancer	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	$864,000**
22	RP190435	IIRA	2.4	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000
23	RP190295	IIRA	2.4	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***
24	RP190326	IIRA	2.4	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000
25	RP190218	IIRA	2.5	Deciphering the Underlying Biology and Translational Relevance of PD-L2	Curran, Michael A	The University of Texas M. D. Anderson Cancer Center	$900,000
26	RP190252	IIRA	2.5	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000
27	RP190210	IIRAP	2.5	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527
28	RP190132	IIRACCA	2.5	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006
29	RP190385	IIRACCA	2.6	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000
30	RP190360	IIRACT	2.6	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991
31	RP190029	IIRA	2.7	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000

32	RP190131	IIRA	2.7	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907
33	RP190235	IIRA	2.8	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747
34	RP190002	IIRACCA	2.8	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218
35	RP190233	IIRACCA	2.8	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000
36	RP190454	IIRA	2.9	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000
37	RP190211	IIRA	2.9	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927
38	RP190251	IIRA	3.0	Defining and Enabling Delivery of microRNA and CRISPR Therapeutics for Hepatocellular Carcinoma (HCC)	Siegwart, Daniel J	The University of Texas Southwestern Medical Center	$900,000
39	RP190414	IIRACCA	3.1	Biochemical and Genetic Interrogation of EWSR1-FLI1 in Ewing Sarcoma	McFadden, David G	The University of Texas Southwestern Medical Center	$1,200,000
40	RP190287	IIRA	3.1	Regulation of CD8 T-Cell Responses in Antitumor Immunity	Sun, Shao-Cong	The University of Texas M. D. Anderson Cancer Center	$900,000
41	RP190421	IIRA	3.1	Structure-Based Drug Design of Inhibitors for a Breast Cancer Signature Kinase	Goldsmith, Elizabeth J	The University of Texas Southwestern Medical Center	$900,000
42	RP190346	IIRACB	3.3	Predicting Drug Response From Genomic Data Using Deep Learning Methods	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$892,157

43	RP190366	IIRA	**3.3**	Characterization and Optimization of Novel Allosteric KRAS Inhibitors	Gorfe, Alemayehu A	The University of Texas Health Science Center at Houston	$897,483
44	RP190208	IIRACB	**3.4**	Dissecting Cellular Heterogeneity of Bulk Tumors for Prediction of Overall Survival and Responsive Patients to Immunotherapy	Wang, Tao	The University of Texas Southwestern Medical Center	$900,000
45	RP190401	IIRACCA	**3.4**	A Mouse Model for Studying DIPG Initiation and Progression in the Pons	Xie, Zhigang	Texas A&M University System Health Science Center	$721,306
46	RP190358	IIRA	**3.4**	The Role of ZMYND8 in Breast Cancer Stem Cells and Tumor Progression	Luo, Weibo	The University of Texas Southwestern Medical Center	$900,000
47	RP190259	IIRA	**3.4**	Role of the N6-Methyladenosine (m6A) Writer METTL3/METTL14 in Cancer	Nam, Yunsun	The University of Texas Southwestern Medical Center	$900,000

*RP190135 – PI withdrew application POST- SRC recommendation and PRE-PIC meeting
**RP190077 reflects budget as reduced by the SRC. SRC recommended the removal of the 3rd aim.
*** RP190295 SRC recommended requiring 10% effort for PI in order to fund.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Individual Investigator Research Awards for Clinical Translation

Request for Applications

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-19.1-IIRACT

Individual Investigator Research Awards for Clinical Translation

Please also refer to the Instructions for Applicants document, which will be posted on March 7, 2018

Application Receipt Opening Date: March 7, 2018

Application Receipt Closing Date: June 6, 2018

FY 2019
Fiscal Year Award Period
September 1, 2018–August 31, 2019

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RFA VERSION HISTORY

Rev 1/11/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas (liver cancers)

2. RATIONALE

This Individual Investigator Research Awards for Clinical Translation (IIRACT) mechanism will support the conduct of hypothesis-based studies of novel cancer therapies or devices in early-phase clinical trials or completed trials where the outcome is known. Such clinical trials offer important opportunities to incorporate biomarkers, pharmacokinetic and pharmacodynamic monitoring, and/or imaging studies to provide more precise knowledge about what works, in whom, and in which types of cancer and to guide subsequent clinical development of a novel cancer therapy.

The research supported by this mechanism is important because current clinical development of novel cancer therapeutics remains slow and expensive with many late-stage failures. Only 5% of cancer therapeutics that enter clinical evaluation will be approved, and the approval process is often measured in decades. There is an urgent need to accelerate and enhance the efficiency of this process by improving the clinical evaluation of novel cancer therapeutics through adoption of modern trial designs that incorporate biomarkers. Such trials will build on advances in basic discovery that have identified the critical targets involved in the hallmarks of cancer and have led to mechanism-based therapeutics. Trials that are designed to determine if predictors of response and efficacy identified in preclinical models also occur in patients have the potential to accelerate therapeutic development and approvals. They also guide the development of diagnostic tests to identify those patients most likely to benefit from these new treatments. Well-conducted early-phase studies will also inform reasons for treatment failure and feed back to preclinical studies designed to overcome barriers to success identified in patients.

3. RESEARCH OBJECTIVES

The goal of the IIRACT Award is to promote clinical research that will lead to a better understanding of the clinical efficacy of a cancer therapy or diagnostic device. Applications submitted under this mechanism should propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known.

Clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices are all responsive to this Request for Applications (RFA).

Applications that propose the development and validation of a biomarker (biospecimen derived from patient tissue or biofluid) or an imaging biomarker are responsive to this RFA provided that the research plan includes validation steps that involve patients treated on a clinical trial.

Early-phase clinical trials of agents or combinations of agents for which there are robust nonclinical data that suggest there may be clinical activity are responsive to the RFA, even if there is no biomarker, as long as the early-phase clinical trial will lead to determining if the activity observed in the laboratory can be replicated in patients.

Additional examples of the types of studies appropriate for the IIRACT award include, but are not limited to, the following:

- Exploratory, phase 1, or small phase 2 trials of new agents, repurposed agents, radiation therapy, surgery, or combinations of interventions where the trial design incorporates biomarker and/or imaging strategies to determine one or more of the following: presence of the drug target, target inhibition, biological pathway inhibition, or pathophysiological alteration by the investigational drug or device
- Discovery and/or validation of predictive biomarkers (eg, genomic, proteomic, or metabolomic signatures of response) using biospecimens from trials where the outcome is known
- Correlation of the activation of specific signaling pathways with clinical outcomes
- Pharmacogenomic studies aimed at the identification of genomic profiles associated with increased/decreased efficacy or toxicity during clinical interventions
- Discovery and/or early validation of biomarkers elucidating mechanisms of action of interventions aimed at preventing or treating symptoms and/or toxicities resulting from treatment using biospecimens from clinical trials where the outcomes are known
- Molecular analyses of biospecimens obtained from exceptional responders

4. FUNDING INFORMATION

- Applicants may request a maximum of $400,000 per year for a period of up to 3 years.
- Applicants who plan on conducting a clinical trial as part of the project may request up to $600,000 in total costs per year for up to 4 years. Note that an individual detailed budget for conducting a clinical trial is required.

- Exceptions to these limits may be requested if extremely well justified.
- If a clinical trial is proposed, the budget justification must include a timeline for trial initiation and accrual targets.
- If a clinical trial is proposed, applications should provide documentation that the proposed trial is feasible within the project timeline. For example, drug access through an industry or CTEP arrangement should be documented. When indicated, an approved investigational new drug application (IND) or investigational device exemption (IDE) for devices from the Food and Drug Administration (FDA) should be cited, or if no IND is yet available for the agent(s), then a pre-IND meeting would have been held with the FDA, and the summary letter from that pre-IND meeting would be included as an attachment (see section 8.2.10).
- Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs including diagnostic or interventional procedures associated with participation in a clinical trial and not considered routine patient care, and travel to scientific/technical meetings or collaborating institutions (see section 8.2.12).

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism.
- A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Research Program.
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may not submit applications to this RFA and to RFA-R-19.1-IIRA, RFA-R-19.1-IIRACB, RFA-R-19.1-IIRACCA, or RFA R-19.1-IIRAP. Only 1 IIRA, IIRACT, IIRACB, IIRACCA, or IIRAP application per cycle is allowed. A PI may submit only 1 new or resubmission application under this RFA during this funding cycle. If submitting a renewal application, a PI may submit both a new or resubmission application and a renewal application under this RFA during this funding cycle.

- A PI may be a Co-PI on applications submitted to this RFA and to RFA-R-19.1-IIRACB, RFA-R-19.1-IIRACCA, RFA R-19.1-IIRA, or RFA R-19.1-IIRAP.
- A PI may submit both a new application to this RFA and a renewal application to another RFA during this funding cycle.
- An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants. Recruitment Grants and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers MIRA Project Co-PIs equivalent to a PI. For the purpose of calculating the number of active grants, CPRIT will consider the number of active grants at the time of the award contract effective date (for this cycle expected to be March 1, 2019).
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included.
- Collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant

funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. This policy is in effect for all applications submitted to date. See section 8.2.5.

7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA, IIRACCA, or IIRAP that is appropriate for the IIRACT mechanism may be submitted under this RFA for a competitive renewal. See section 8.2.6. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See section 9.2.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also

create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 7, 2018, and must be submitted by 4 PM central time on June 6, 2018. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

Please note that deadline extension requests are very rarely approved.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 5 will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. **Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1).** Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and

therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan.

Clearly address how the proposed project, if successful, will have a major impact on cancer.

Summarize how the proposed research creates new paradigms or challenges existing ones.

Indicate whether this research plan represents a new direction for the PI.

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the layperson's summary. The layperson's summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications.

If a clinical trial is proposed as a component of this application, the timeline must include clearly defined patient accrual milestones.

If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (2 pages)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh research plan or modify the original research plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (2 Pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (11 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required. This section has been lengthened to allow the applicant to present the statistical considerations used to determine a trial design, accrual milestones, and biomarker validation.

8.2.8. Vertebrate Animals and/or Human Subjects (2 pages)

If vertebrate animals will be used, provide a detailed plan of the protocols that will be followed. If human subjects or human biological samples will be used, provide a detailed plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism. If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

8.2.9. Protocol Documentation

If a clinical trial is planned, a PDF copy of the full protocol can be attached.

8.2.10. Investigational New Drug Application (IND)/Investigational Device Exemption (IDE)

If a clinical trial is proposed that requires an IND or IDE, provide evidence of an approved IND or IDE for devices from the FDA. If no IND is yet available for the agent(s), then provide a summary letter from a pre-IND meeting held with the FDA. If the drug or device is to be provided through an industry or CTEP mechanism, provide documentation that the drug or device will be available.

8.2.11. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.12. Budget and Justification

Provide a compelling and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, costs associated with the conduct of a clinical trial, animal care costs, and other expenses. While there will be 1 budget for the entire project, an individual budget and budget justification for the conduct of a clinical trial must be included. The justification should include the statistical considerations that led to the clinical trial design, accrual milestones, and validation of biomarkers.

Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of

the proposed budget, include a special and clearly labeled section in the budget justification that explains the request.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2019 is $200,000; CPRIT FY 2019 is from September 1, 2018, through August 31, 2019. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.13. Biographical Sketches (5 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research.

A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

8.2.14. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.15. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.16. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

8.3. Formatting Instructions

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English.
- **Document Format:** PDF only.
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Line Spacing:** Single.
- **Page Size:** 8.5 x 11 inches.
- **Margins:** 0.75 inch, all directions.

- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.
- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. Include URLs of publications referenced in the application.

  Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135: 45–67.

- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed in section 9.4. Applicants will be notified of peer review panel assignments prior to the peer review meeting dates. Peer review panel membership can be found on the CPRIT website. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Research Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and

subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and expertise to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage-specific fashion. Have early-career–stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percent effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This is a critical criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.
Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: Is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed?

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA	
RFA release	January 11, 2018
Application	
Online application opens	March 7, 2018, 7 AM central time
Application due	June 6, 2018, 4 PM central time
Application review	August–October 2018
Award	
Award notification	February 20, 2019
Anticipated start date	March 1, 2019

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to

exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. A grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the 5% indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding. The

demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time.

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Academic Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-1 Peer Review Meeting
(19.1_ACR_BCR-1)
Observation Report

Report No.	2018-10-19 19.1_ACR_BCR-1
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-1_Peer Review Meeting (19.1_ACR_BCR-1)
Panel Date:	10-19-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-1_Peer Review (19.1_ACR_BCR-1) meeting. The meeting was chaired by Thomas Curran and conducted via in-person in Dallas, Texas on October 19, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and eighteen (18) were not discussed
- Panelists: One (1) panel chair and fourteen (14) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

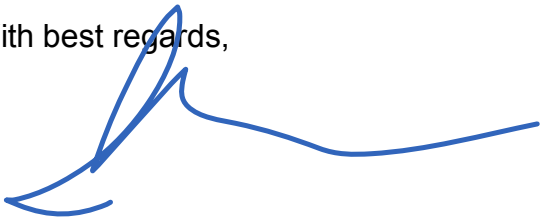
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-2 Peer Review Meeting
(19.1_ACR_BCR-2)
Observation Report

Report No.	2018-10-23 19.1_ACR_BCR-2
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-2_Peer Review Meeting (19.1_ACR_BCR-2)
Panel Date:	10-23-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-2_Peer Review (19.1_ACR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via in-person in Dallas, Texas on October 23, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and fifteen (15) were not discussed
- Panelists: One (1) panel chair and seventeen (17) expert reviewers and one (1) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and two (2) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

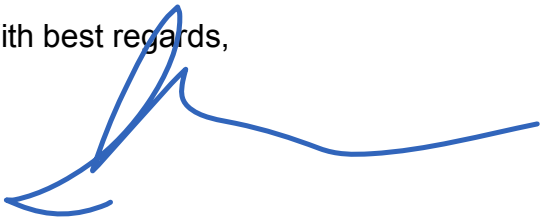
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Biology Peer Review Meeting (19.1 ACR CB)
Observation Report

Report No.	2018-10-22 19.1_ACR_CB
Program Name:	Academic Research
Panel Name:	Cancer Biology Peer Review Meeting (19.1_ACR_CB)
Panel Date:	10/22/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Biology Peer Review (19.1_ACR_CB) meeting. The meeting was chaired by Peter Jones and conducted via in-person in Dallas, Texas on October 22, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and nineteen (19) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were five (5) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

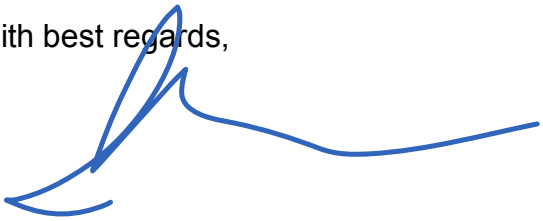
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Prevention Research Peer Review Meeting
(19.1_ACR_CPR)
Observation Report

Report No.	2018-10-24 19.1_ACR_CPR
Program Name:	Academic Research
Panel Name:	Cancer Prevention Research Peer Review Meeting (19.1_ACR_CPR)
Panel Date:	10/24/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Prevention Research Peer Review (19.1_ACR_CPR) meeting. The meeting was chaired by Thomas Sellars and conducted via in-person in Dallas, Texas on October 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eighteen (18) applications were discussed and fourteen (14) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eighteen (18) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

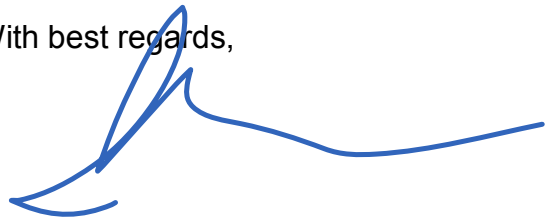
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Clinical/Translational Cancer Research Peer Review Meeting
(19.1 ACR C/TCR)
Observation Report

Report No.	2018-10-25 19.1_ACR_C/TCR
Program Name:	Academic Research
Panel Name:	Clinical/Translational Cancer Research Peer Review Meeting (19.1_ACR_C/TCR)
Panel Date:	10/25/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Clinical/Translational Cancer Research Peer Review (19.1_ACR_C/TCR) meeting. The meeting was chaired by Margaret Tempero and Richard O'Reilly and conducted via in-person in Dallas, Texas on October 25, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and twenty-one (21) were not discussed
- Panelists: Two (2) panel chairs, twenty-three (23) expert reviewers and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were ten (10) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

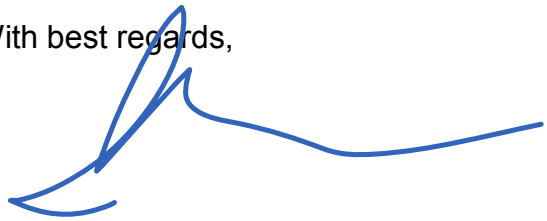
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Imaging Technology and Informatics Review Meeting
(19.1_ACR_ITI)
Observation Report

Report No.	2018-10-18 19.1_ACR_ITI
Program Name:	Academic Research
Panel Name:	Imaging Technology and Informatics Review Meeting (19.1_ACR_ITI)
Panel Date:	10/18/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Imaging Technology and Informatics Review Meeting (19.1_ITI) meeting. The meeting was chaired by Sanjiv Sam Gambhir and conducted via in-person in Dallas, Texas on October 18, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seventeen (17) applications were discussed and twenty-one (21) were not discussed
- Panelists: One (1) panel chair and twenty (20) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

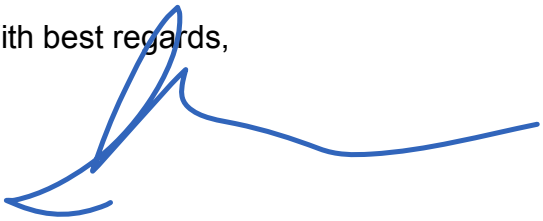
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)

19.1 Scientific Review Council Meeting (19.1 SRC) Observation Report

Report No. 2018-12-05 19.1_SRC
Program Name: Academic Research
Panel Name: 19.1 Scientific Review Council Meeting (19.1_SRC)
Panel Date: 12/05/2018
Report Date: 12/05/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Scientific Review Council Meeting (19.1_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via or teleconference on December 5, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Forty-seven (47) applications were discussed and zero (0) were not discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

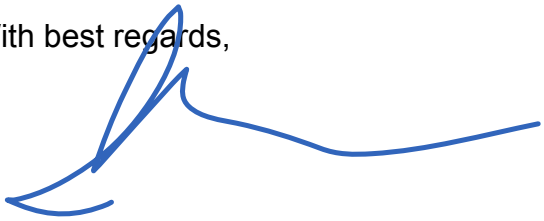
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Academic Research 19.1 Applications
(Academic Research Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 19.1 include *Individual Investigator Research Awards, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Clinical Translation, Individual Investigator Research Awards for Computational Biology,* and *Individual Investigator Research Awards for Prevention and Early Detection.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP190414pe/ RP190414	David McFadden	The University of Texas Southwestern Medical Center	M. McMahon
RP190077pe/ RP190077	Cheng-Ming Chiang	The University of Texas Southwestern Medical Center	T. Kodadek
RP190301pe	Ilya Finkelstein	The University of Texas at Austin	A. Tomkinson;C. Prives;W. Chazin
RP190301	Ilya Finkelstein	The University of Texas at Austin	J. Manley
RP190421pe/ RP190421	Elizabeth Goldsmith	The University of Texas Southwestern Medical Center	A. Tomkinson;T. Kodadek
RP190398pe	Rachel Schiff	Baylor College of Medicine	G. Greene
RP190398	Rachel Schiff	Baylor College of Medicine	A. Tonachel;G. Greene
RP190210pe/ RP190210	Robert Volk	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon

Application ID	Applicant/PI	Institution	Conflict Noted
RP190326pe/ RP190326	Roza Nurieva	The University of Texas M. D. Anderson Cancer Center	S. Dubinett;V. Engelhard
RP190019pe/ RP190019	Eva Sevick	The University of Texas Health Science Center at Houston	A. Wu
RP190211pe/ RP190211	Mark Pagel	The University of Texas M. D. Anderson Cancer Center	J. Basilion
Applications not considered by the PIC or Oversight Committee			
RP190464pe/ RP190464	Everett Stone	The University of Texas at Austin	G. Prendergast
RP190087pe/ RP190087*	John Tainer	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson;W. Chazin
RP190203pe/ RP190203*	Pawel Mazur	The University of Texas M. D. Anderson Cancer Center	N. Bardeesy
RP190314pe	Jason Huse	The University of Texas M. D. Anderson Cancer Center	J. Petrini
RP190332pe/ RP190332*	Steven Millward	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson
RP190078pe/ RP190078*	Ralf Krahe	The University of Texas M. D. Anderson Cancer Center	J. Issa
RP190245pe	Yunfei Wen	The University of Texas M. D. Anderson Cancer Center	M. Hollingsworth
RP190356pe/ RP190356*	Jung-whan Kim	The University of Texas at Dallas	M. Hollingsworth
RP190458pe/ RP190458	Robert Chapkin	Texas AgriLife Research	E. Fearon
RP190039pe/ RP190039*	Divya Patel	The University of Texas Health Center at Tyler	T. Brandon
RP190044pe/ RP190044	Jason Robinson	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190054pe/ RP190054	Sheng Pan	The University of Texas Health Science Center at Houston	C. Li;G. Petersen;W. Barlow

Application ID	Applicant/PI	Institution	Conflict Noted
RP190062pe/ RP190062	Wenyi Wang	The University of Texas M. D. Anderson Cancer Center	L. Mucci
RP190068pe/ RP190068*	Jian Gu	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190139pe/ RP190139	Alexander Prokhorov	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190232pe/ RP190232*	Manal Hassan	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190281pe	Olena Weaver	The University of Texas M. D. Anderson Cancer Center	C. Li
RP190321pe/ RP190321*	Lindsay Cowell	The University of Texas Southwestern Medical Center	C. Li;W. Barlow
RP190357pe/ RP190357	Subrata Sen	The University of Texas M. D. Anderson Cancer Center	G. Petersen;W. Barlow
RP190479pe/ RP190479*	Xuexia Wang	University of North Texas	L. Kushi
RP190016pe	Damith Udugamasooriya	University of Houston	S. Dubinett
RP190148pe/ RP190148*	Chun Li	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190166pe/ RP190166*	Khandan Keyomarsi	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190181pe/ RP190181*	Maria Teresa Bertilaccio	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190219pe/ RP190219*	Han Liang	The University of Texas M. D. Anderson Cancer Center	S. Dubinett
RP190222pe/ RP190222	Scott Kopetz	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190253pe/ RP190253*	Anil Korkut	The University of Texas M. D. Anderson Cancer Center	G. Powis

Application ID	Applicant/PI	Institution	Conflict Noted
RP190341pe/ RP190341*	Lawrence Kwong	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190352pe	Y. Alan Wang	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190371pe/ RP190371*	Charles Reynolds	Texas Tech University Health Sciences Center	W. Kast
RP190481pe	Justyn Jaworski	The University of Texas at Arlington	S. Dubinett
RP190058pe/ RP190058*	David Fetzer	The University of Texas Southwestern Medical Center	K. Zinn
RP190076pe/ RP190076*	Kenneth Hoyt	The University of Texas at Dallas	J. Basilion;K. Zinn
RP190119pe	Rahul Sheth	The University of Texas M. D. Anderson Cancer Center	W. Cai
RP190164pe/ RP190164*	Anna Sorace	The University of Texas at Austin	K. Zinn
RP190244pe/ RP190244*	Lilie Lin	The University of Texas M. D. Anderson Cancer Center	D. Mankoff
RP190277pe	Kevin Burgess	Texas A&M University	W. Cai
RP190304pe/ RP190304	Baowei Fei	The University of Texas at Dallas	J. Basilion
RP190438pe	Mihaela Stefan	The University of Texas at Dallas	K. Zinn
RP190263	Ricardo Aguiar	The University of Texas Health Science Center at San Antonio	M. McMahon

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards for Clinical Translation

Academic Research Cycle 19.1

Final Scores for Fully Reviewed Applications

Application ID	Final Overall Evaluation Score
RP190067*	1.1
RP190049*	1.2
RP190135*	1.9
RP190160*	2.2
RP190360*	2.6
Pa	3.4
Pb	3.5
Pc	3.7
Pd	3.7
Pe	3.8
Pf	4.0
Pg	4.0
Ph	4.1
Pi	4.2
Pj	4.3
Pk	4.3
Pl	4.7
Pm	4.7
Pn	4.7
Po	5.0
Pp	5.0
Pq	5.0
Pr	5.7

* Recommended for award

Individual Investigator Research Awards for Clinical Trials

Academic Research Cycle 19.1

Final Scores for Preliminary Evaluation

These are the final overall evaluation scores for applications receiving preliminary evaluation that did not move forward to full review. The final overall evaluation score is an average of the preliminary evaluation scores assigned to each application by the primary reviewers.

Application ID	Final Overall Evaluation Score
Ga	3.7
Gb	3.7
Gc	3.7
Gd	3.7
Ge	3.7
Gf	4.3
Gg	4.3
Gh	5.0
Gi	5.3
Gj	5.7

Final Overall Evaluation Scores and Rank Order Scores

LUDWIG
CANCER
RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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T 858 534 7804
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January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Individual Investigator Research Awards (IIRA), the Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), the Individual Investigator Research Awards for Clinical Translation (IIRACT), the Individual Investigator Research Awards for Computational Biology (IIRACB) and the Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on December 5, 2018 to consider the applications recommended by the peer review panels following their meetings that were held October 18, 2018 – October 25, 2018. Please note that RP190135 is included in the list below because it was recommended by the SRC; however, the application was subsequently withdrawn by the applicant.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The total amount for the applications recommended is $50,055,527.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
1	RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252
2	RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000
3	RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577
4	RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892
5	RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473
6	RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433
7	RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000
8	RP190135	IIRACT	**1.9**	Preventing Chemoradiation Bone Marrow Toxicities With FLT PET and SOD Mimics	McGuire, Sarah	The University of Texas Southwestern Medical Center	$2,087,928*
9	RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction in Childhood Cancer Survivors	Noel, Cory V	Baylor College of Medicine	$1,192,412
10	RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000

11	RP190398	IIRA	**2.0**	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566
12	RP190019	IIRA	**2.0**	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000
13	RP190278	IIRA	**2.0**	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000
14	RP190192	IIRA	**2.1**	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000
15	RP190236	IIRA	**2.1**	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397
16	RP190279	IIRAP	**2.2**	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung Carcinogenesis by Omega-3 Fatty Acids	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151
17	RP190160	IIRACT	**2.2**	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000
18	RP190107	IIRACB	**2.3**	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185
19	RP190256	IIRA	**2.4**	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992

20	RP190301	IIRA	2.4	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000
21	RP190077	IIRA	2.4	Molecular Action of Phospho-BRD4–Targeting Compounds in Breast Cancer	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	$864,000**
22	RP190435	IIRA	2.4	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000
23	RP190295	IIRA	2.4	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***
24	RP190326	IIRA	2.4	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000
25	RP190218	IIRA	2.5	Deciphering the Underlying Biology and Translational Relevance of PD-L2	Curran, Michael A	The University of Texas M. D. Anderson Cancer Center	$900,000
26	RP190252	IIRA	2.5	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000
27	RP190210	IIRAP	2.5	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527
28	RP190132	IIRACCA	2.5	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006
29	RP190385	IIRACCA	2.6	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000
30	RP190360	IIRACT	2.6	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991
31	RP190029	IIRA	2.7	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000

32	RP190131	IIRA	2.7	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907
33	RP190235	IIRA	2.8	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747
34	RP190002	IIRACCA	2.8	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218
35	RP190233	IIRACCA	2.8	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000
36	RP190454	IIRA	2.9	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000
37	RP190211	IIRA	2.9	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927
38	RP190251	IIRA	3.0	Defining and Enabling Delivery of microRNA and CRISPR Therapeutics for Hepatocellular Carcinoma (HCC)	Siegwart, Daniel J	The University of Texas Southwestern Medical Center	$900,000
39	RP190414	IIRACCA	3.1	Biochemical and Genetic Interrogation of EWSR1-FLI1 in Ewing Sarcoma	McFadden, David G	The University of Texas Southwestern Medical Center	$1,200,000
40	RP190287	IIRA	3.1	Regulation of CD8 T-Cell Responses in Antitumor Immunity	Sun, Shao-Cong	The University of Texas M. D. Anderson Cancer Center	$900,000
41	RP190421	IIRA	3.1	Structure-Based Drug Design of Inhibitors for a Breast Cancer Signature Kinase	Goldsmith, Elizabeth J	The University of Texas Southwestern Medical Center	$900,000
42	RP190346	IIRACB	3.3	Predicting Drug Response From Genomic Data Using Deep Learning Methods	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$892,157

43	RP190366	IIRA	**3.3**	Characterization and Optimization of Novel Allosteric KRAS Inhibitors	Gorfe, Alemayehu A	The University of Texas Health Science Center at Houston	$897,483
44	RP190208	IIRACB	**3.4**	Dissecting Cellular Heterogeneity of Bulk Tumors for Prediction of Overall Survival and Responsive Patients to Immunotherapy	Wang, Tao	The University of Texas Southwestern Medical Center	$900,000
45	RP190401	IIRACCA	**3.4**	A Mouse Model for Studying DIPG Initiation and Progression in the Pons	Xie, Zhigang	Texas A&M University System Health Science Center	$721,306
46	RP190358	IIRA	**3.4**	The Role of ZMYND8 in Breast Cancer Stem Cells and Tumor Progression	Luo, Weibo	The University of Texas Southwestern Medical Center	$900,000
47	RP190259	IIRA	**3.4**	Role of the N6-Methyladenosine (m6A) Writer METTL3/METTL14 in Cancer	Nam, Yunsun	The University of Texas Southwestern Medical Center	$900,000

*RP190135 – PI withdrew application POST- SRC recommendation and PRE-PIC meeting
**RP190077 reflects budget as reduced by the SRC. SRC recommended the removal of the 3rd aim.
*** RP190295 SRC recommended requiring 10% effort for PI in order to fund.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Individual Investigator Research Awards for Prevention and Early Detection

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-19.1-IIRAP

Individual Investigator Research Awards for Prevention and Early Detection

Please also refer to the Instructions for Applicants document, which will be posted on March 7, 2018

Application Receipt Opening Date: March 7, 2018

Application Receipt Closing Date: June 6, 2018

FY 2019
Fiscal Year Award Period
September 1, 2018–August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 1/11/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas (liver cancers)

2. RATIONALE

A major opportunity for investment in cancer research is in the area of cancer prevention. Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This has the added advantage of sparing people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer therapies, and the financial burdens associated with cancer treatment.

Identification of causes of cancer, including environmental chemicals, microbial agents, and genetic susceptibilities, is essential for reducing cancer incidence. In addition, intervening in the process at early stages of cancer development, before genetic instability becomes widespread, holds promise of successfully eliminating cells destined to become cancer cells. Basic research on the identification and control of premalignant cells, the role of the tumor cell microenvironment in tumor development, environmental drivers, and predictive markers of cancer progression from normal to neoplastic may provide new avenues for intervening early in the process of cancer development. Early detection of cancer using biomarkers and early screening methods also can reduce morbidity and mortality from cancer.

Although CPRIT is required to spend 10% of its budget on cancer prevention, CPRIT's Cancer Prevention Program focuses exclusively on the delivery of evidence-based interventions to underserved populations and does not fund prevention research. Thus, there is a unique opportunity for CPRIT's Academic Research Program to fund research on adoption of cancer-preventing behaviors, effectiveness of various interventions, and how best to deliver prevention services that could eventually result in implementation through the Prevention Program.

3. RESEARCH OBJECTIVES

This Request for Applications (RFA) solicits applications for innovative research projects addressing questions that will advance current knowledge of the causes, prevention, early-stage progression from normal to neoplastic cells, and/or the early detection of cancer. Research projects that propose to conduct implementation research designed to accelerate the adoption and deployment of sustainable, evidence-based cancer prevention and screening interventions at multiple levels and in different clinical and community settings are encouraged.

Applications may address any topic or issue related to cancer causation, prevention, early progression, early detection, or implementation of evidence based interventions. Research may be laboratory-, clinical-, or population-based and may include behavioral/intervention, dissemination, or health services/outcomes research to reduce cancer incidence or promote early

detection. CPRIT expects the outcomes of activities supported by this mechanism to reduce the burden of cancer in the near or long term. CPRIT encourages applications that seek to apply or develop state-of-the-art technologies, tools, and/or resources for prevention or early detection of cancer, including those with potential commercialization opportunities. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies. Partnering with cancer biologists or oncologists is highly recommended for Principal Investigators (PIs) who do not have this expertise.

The subject of applications may include, but is not limited to, the following:

- Environmental carcinogenesis, including high-throughput methods for carcinogen detection and identification of carcinogens and their mechanisms of action
- Role of microbial agents in cancer causation
- Cancer epidemiology
- Identification of populations at high risk of developing cancer
- Cellular and molecular alterations leading to development of precancerous lesions
- Approaches to prevent progression of normal to preneoplastic cells to cancer cells
- Methods for early detection of cancer
- Development and testing of intervention strategies to increase access to and improve recently endorsed screening technologies for cancer
- Cancer-focused health services/outcomes or patient-centered outcomes research
- Development and adaptation of novel interventions for effective and efficient delivery of cancer prevention and screening services

The *degree of relevance* to reducing the burden of cancer is a critical criterion for evaluation of projects for funding by CPRIT (section 9.4.1).

4. FUNDING INFORMATION

Applicants may request a maximum of $300,000 in total costs per year for up to 3 years for laboratory and clinical research and up to $500,000 in total costs per year for up to 3 years for population-based research, including implementation research designed to accelerate the adoption and deployment of sustainable, evidence-based cancer prevention and screening interventions at multiple levels and in different clinical and community settings. Exceptions to these limits may be requested if extremely well justified (see section 8.2.10). Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support

construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Research Program.
- The PI must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may not submit applications to this RFA and to RFA-R-19.1-IIRA, RFA-R-19.1-IIRACB, RFA-R-19.1-IIRACCA, or RFA R-19.1-IIRACT. Only 1 IIRA, IIRACT, IIRACB, IIRACCA, or IIRAP application per cycle is allowed. A PI may submit only 1 new or resubmission application under this RFA during this funding cycle. If submitting a renewal application, a PI may submit both a new or resubmission application and a renewal application under this RFA during this funding cycle.
- An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants. Recruitment Grants and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers MIRA Project Co-PIs equivalent to a PI. For the purpose of calculating the number of active grants, CPRIT will consider the number of active grants at the time of the award contract effective date (for this cycle expected to be March 1, 2019).
- A PI may be a Co-PI on applications submitted to this RFA and to RFA-R-191-IIRACT, RFA-R-19.1-IIRACB, RFA-R-19.1-IIRA, or RFA-R-19.1-IIRACCA.
- Applications that address untargeted research, Cancers in Children and Adolescents, Clinical Translation, or Computational Biology should be submitted under the appropriate targeted RFA.
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included. Collaborators should have specific and well-defined roles.

- Collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would

be considered a resubmission. This policy is in effect for all applications submitted to date. See section 8.2.5.

7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA that is appropriate for the IIRAP mechanism may be submitted under this RFA for a competitive renewal. See section 8.2.6. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See section 9.2.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 7, 2018, and must be submitted by 4 PM central time on June 6, 2018. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk, within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records. Please note that deadline extension requests are very rarely approved.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 5 will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. **Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1).** Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the layperson's summary. The layperson's summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (2 pages)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh research plan or modify the original research plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

8.2.8. Vertebrate Animals and/or Human Subjects (2 pages)

If vertebrate animals will be used, provide a detailed plan of the protocols that will be followed. If human subjects or human biological samples will be used, provide a detailed plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism. If vertebrate animals and/or human subjects are included in the proposed research, reference biostatistical input for sample selection and evaluation. In addition, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Do not exceed $300,000 per year for laboratory and clinical studies, and $500,000 for population-based studies, including implementation research designed to accelerate the adoption and deployment of sustainable, evidence-based cancer prevention and screening interventions at multiple levels and in different clinical and community settings. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2019 is $200,000; CPRIT FY 2019 is from September 1, 2018, through August 31, 2019. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. Biographical Sketches (5 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

8.2.12. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.13. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.14. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

8.3. Formatting Instructions

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English.
- **Document Format:** PDF only.
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Line Spacing:** Single.
- **Page Size:** 8.5 x 11 inches.
- **Margins:** 0.75 inch, all directions.
- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.
- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. Include URLs of publications referenced in the application.

Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135: 45–67.

- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent

peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed in section 9.4. Applicants will be notified of peer review panel assignments prior to the peer review meeting dates. Peer review panel membership can be found on the CPRIT website. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a

Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Research Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient

preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and expertise to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage–specific fashion. Have early-career-stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percent effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer prevention research or early detection? This is a critical criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: Is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed?

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release	January 11, 2018

Application

Online application opens	March 7, 2018, 7 AM central time
Application due	June 6, 2018, 4 PM central time
Application review	August–October 2018

Award

Award notification	February 20, 2019
Anticipated start date	March 1, 2019

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In

addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. A grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the 5% indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time.

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Academic Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-1 Peer Review Meeting
(19.1_ACR_BCR-1)
Observation Report

Report No.	2018-10-19 19.1_ACR_BCR-1
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-1_Peer Review Meeting (19.1_ACR_BCR-1)
Panel Date:	10-19-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-1_Peer Review (19.1_ACR_BCR-1) meeting. The meeting was chaired by Thomas Curran and conducted via in-person in Dallas, Texas on October 19, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and eighteen (18) were not discussed
- Panelists: One (1) panel chair and fourteen (14) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

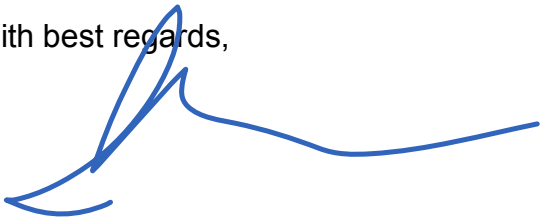
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Basic Cancer Research-2 Peer Review Meeting
(19.1_ACR_BCR-2)
Observation Report

Report No.	2018-10-23 19.1_ACR_BCR-2
Program Name:	Academic Research
Panel Name:	Basic Cancer Research-2_Peer Review Meeting (19.1_ACR_BCR-2)
Panel Date:	10-23-18
Report Date:	10-30-18

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Basic Cancer Research-2_Peer Review (19.1_ACR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via in-person in Dallas, Texas on October 23, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and fifteen (15) were not discussed
- Panelists: One (1) panel chair and seventeen (17) expert reviewers and one (1) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and two (2) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

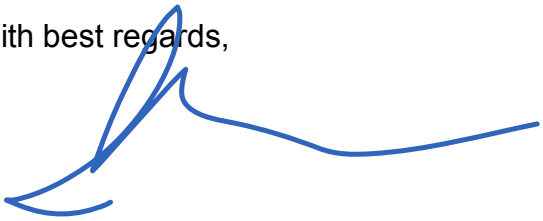
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Biology Peer Review Meeting (19.1 ACR CB)
Observation Report

Report No.	2018-10-22 19.1_ACR_CB
Program Name:	Academic Research
Panel Name:	Cancer Biology Peer Review Meeting (19.1_ACR_CB)
Panel Date:	10/22/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Biology Peer Review (19.1_ACR_CB) meeting. The meeting was chaired by Peter Jones and conducted via in-person in Dallas, Texas on October 22, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-one (21) applications were discussed and nineteen (19) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were five (5) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

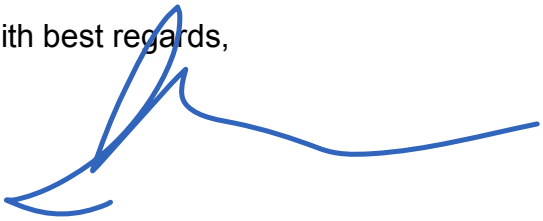
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Cancer Prevention Research Peer Review Meeting
(19.1_ACR_CPR)
Observation Report

Report No.	2018-10-24 19.1_ACR_CPR
Program Name:	Academic Research
Panel Name:	Cancer Prevention Research Peer Review Meeting (19.1_ACR_CPR)
Panel Date:	10/24/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Cancer Prevention Research Peer Review (19.1_ACR_CPR) meeting. The meeting was chaired by Thomas Sellars and conducted via in-person in Dallas, Texas on October 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eighteen (18) applications were discussed and fourteen (14) were not discussed
- Panelists: One (1) panel chair and fifteen (15) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eighteen (18) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

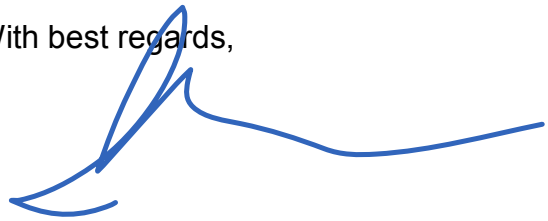
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Clinical/Translational Cancer Research Peer Review Meeting
(19.1 ACR C/TCR)
Observation Report

Report No.	2018-10-25 19.1_ACR_C/TCR
Program Name:	Academic Research
Panel Name:	Clinical/Translational Cancer Research Peer Review Meeting (19.1_ACR_C/TCR)
Panel Date:	10/25/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Clinical/Translational Cancer Research Peer Review (19.1_ACR_C/TCR) meeting. The meeting was chaired by Margaret Tempero and Richard O'Reilly and conducted via in-person in Dallas, Texas on October 25, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twenty-two (22) applications were discussed and twenty-one (21) were not discussed
- Panelists: Two (2) panel chairs, twenty-three (23) expert reviewers and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were ten (10) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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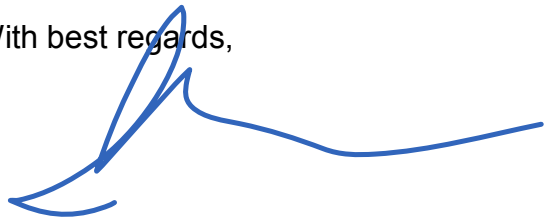
With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Imaging Technology and Informatics Review Meeting
(19.1_ACR_ITI)
Observation Report

Report No.	2018-10-18 19.1_ACR_ITI
Program Name:	Academic Research
Panel Name:	Imaging Technology and Informatics Review Meeting (19.1_ACR_ITI)
Panel Date:	10/18/2018
Report Date:	10/30/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Imaging Technology and Informatics Review Meeting (19.1_ITI) meeting. The meeting was chaired by Sanjiv Sam Gambhir and conducted via in-person in Dallas, Texas on October 18, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seventeen (17) applications were discussed and twenty-one (21) were not discussed
- Panelists: One (1) panel chair and twenty (20) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

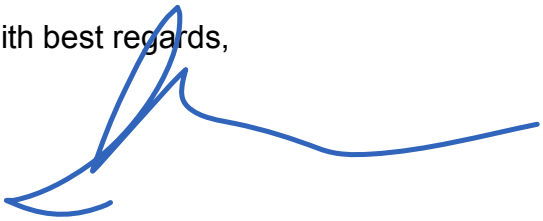
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)

19.1 Scientific Review Council Meeting (19.1 SRC) Observation Report

Report No. 2018-12-05 19.1_SRC
Program Name: Academic Research
Panel Name: 19.1 Scientific Review Council Meeting (19.1_SRC)
Panel Date: 12/05/2018
Report Date: 12/05/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Scientific Review Council Meeting (19.1_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via or teleconference on December 5, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Forty-seven (47) applications were discussed and zero (0) were not discussed
- Panelists: One (1) panel chair and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

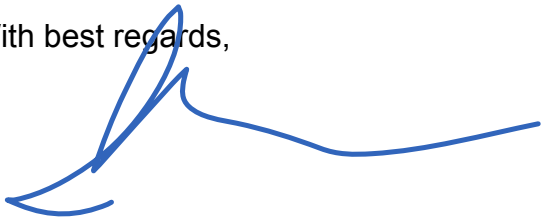
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Academic Research 19.1 Applications
(Academic Research Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 19.1 include *Individual Investigator Research Awards, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Clinical Translation, Individual Investigator Research Awards for Computational Biology,* and *Individual Investigator Research Awards for Prevention and Early Detection.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP190414pe/ RP190414	David McFadden	The University of Texas Southwestern Medical Center	M. McMahon
RP190077pe/ RP190077	Cheng-Ming Chiang	The University of Texas Southwestern Medical Center	T. Kodadek
RP190301pe	Ilya Finkelstein	The University of Texas at Austin	A. Tomkinson;C. Prives;W. Chazin
RP190301	Ilya Finkelstein	The University of Texas at Austin	J. Manley
RP190421pe/ RP190421	Elizabeth Goldsmith	The University of Texas Southwestern Medical Center	A. Tomkinson;T. Kodadek
RP190398pe	Rachel Schiff	Baylor College of Medicine	G. Greene
RP190398	Rachel Schiff	Baylor College of Medicine	A. Tonachel;G. Greene
RP190210pe/ RP190210	Robert Volk	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon

Application ID	Applicant/PI	Institution	Conflict Noted
RP190326pe/ RP190326	Roza Nurieva	The University of Texas M. D. Anderson Cancer Center	S. Dubinett;V. Engelhard
RP190019pe/ RP190019	Eva Sevick	The University of Texas Health Science Center at Houston	A. Wu
RP190211pe/ RP190211	Mark Pagel	The University of Texas M. D. Anderson Cancer Center	J. Basilion
Applications not considered by the PIC or Oversight Committee			
RP190464pe/ RP190464	Everett Stone	The University of Texas at Austin	G. Prendergast
RP190087pe/ RP190087*	John Tainer	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson;W. Chazin
RP190203pe/ RP190203*	Pawel Mazur	The University of Texas M. D. Anderson Cancer Center	N. Bardeesy
RP190314pe	Jason Huse	The University of Texas M. D. Anderson Cancer Center	J. Petrini
RP190332pe/ RP190332*	Steven Millward	The University of Texas M. D. Anderson Cancer Center	A. Tomkinson
RP190078pe/ RP190078*	Ralf Krahe	The University of Texas M. D. Anderson Cancer Center	J. Issa
RP190245pe	Yunfei Wen	The University of Texas M. D. Anderson Cancer Center	M. Hollingsworth
RP190356pe/ RP190356*	Jung-whan Kim	The University of Texas at Dallas	M. Hollingsworth
RP190458pe/ RP190458	Robert Chapkin	Texas AgriLife Research	E. Fearon
RP190039pe/ RP190039*	Divya Patel	The University of Texas Health Center at Tyler	T. Brandon
RP190044pe/ RP190044	Jason Robinson	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190054pe/ RP190054	Sheng Pan	The University of Texas Health Science Center at Houston	C. Li;G. Petersen;W. Barlow

Application ID	Applicant/PI	Institution	Conflict Noted
RP190062pe/ RP190062	Wenyi Wang	The University of Texas M. D. Anderson Cancer Center	L. Mucci
RP190068pe/ RP190068*	Jian Gu	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190139pe/ RP190139	Alexander Prokhorov	The University of Texas M. D. Anderson Cancer Center	R. Schnoll;T. Brandon
RP190232pe/ RP190232*	Manal Hassan	The University of Texas M. D. Anderson Cancer Center	C. Haiman
RP190281pe	Olena Weaver	The University of Texas M. D. Anderson Cancer Center	C. Li
RP190321pe/ RP190321*	Lindsay Cowell	The University of Texas Southwestern Medical Center	C. Li;W. Barlow
RP190357pe/ RP190357	Subrata Sen	The University of Texas M. D. Anderson Cancer Center	G. Petersen;W. Barlow
RP190479pe/ RP190479*	Xuexia Wang	University of North Texas	L. Kushi
RP190016pe	Damith Udugamasooriya	University of Houston	S. Dubinett
RP190148pe/ RP190148*	Chun Li	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190166pe/ RP190166*	Khandan Keyomarsi	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190181pe/ RP190181*	Maria Teresa Bertilaccio	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190219pe/ RP190219*	Han Liang	The University of Texas M. D. Anderson Cancer Center	S. Dubinett
RP190222pe/ RP190222	Scott Kopetz	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190253pe/ RP190253*	Anil Korkut	The University of Texas M. D. Anderson Cancer Center	G. Powis

Application ID	Applicant/PI	Institution	Conflict Noted
RP190341pe/ RP190341*	Lawrence Kwong	The University of Texas M. D. Anderson Cancer Center	V. Engelhard
RP190352pe	Y. Alan Wang	The University of Texas M. D. Anderson Cancer Center	G. Powis
RP190371pe/ RP190371*	Charles Reynolds	Texas Tech University Health Sciences Center	W. Kast
RP190481pe	Justyn Jaworski	The University of Texas at Arlington	S. Dubinett
RP190058pe/ RP190058*	David Fetzer	The University of Texas Southwestern Medical Center	K. Zinn
RP190076pe/ RP190076*	Kenneth Hoyt	The University of Texas at Dallas	J. Basilion;K. Zinn
RP190119pe	Rahul Sheth	The University of Texas M. D. Anderson Cancer Center	W. Cai
RP190164pe/ RP190164*	Anna Sorace	The University of Texas at Austin	K. Zinn
RP190244pe/ RP190244*	Lilie Lin	The University of Texas M. D. Anderson Cancer Center	D. Mankoff
RP190277pe	Kevin Burgess	Texas A&M University	W. Cai
RP190304pe/ RP190304	Baowei Fei	The University of Texas at Dallas	J. Basilion
RP190438pe	Mihaela Stefan	The University of Texas at Dallas	K. Zinn
RP190263	Ricardo Aguiar	The University of Texas Health Science Center at San Antonio	M. McMahon

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards for Prevention & Early Detection

Academic Research Cycle 19.1

Final Scores for Fully Reviewed Applications

Application ID	Final Overall Evaluation Score
RP190022*	1.4
RP190279*	2.2
RP190210*	2.5
Na	2.8
Nb	2.9
Nc	3.1
Nd	3.1
Ne	3.3
Nf	3.4
Ng	3.7
Nh	3.9
Ni	4.0
Nj	4.0
Nk	4.3
Nl	4.3
Nm	4.3
Nn	4.3
No	4.3
Np	4.4
Nq	4.7
Nr	5.0
Ns	5.0
Nt	5.3
Nu	5.3
Nv	5.8
nw	6.0

* Recommended for award

Individual Investigator Research Awards for Prevention & Early Detection

Academic Research Cycle 19.1

Final Scores for Preliminary Evaluation

These are the final overall evaluation scores for applications receiving preliminary evaluation that did not move forward to full review. The final overall evaluation score is an average of the preliminary evaluation scores assigned to each application by the primary reviewers.

Application ID	Final Overall Evaluation Score
Ha	4.0
Hb	4.0
Hc	4.0
Hd	4.7
He	5.0
Hf	5.0
Hg	6.3
Hh	7.0
Hi	7.7

Final Overall Evaluation Scores and Rank Order Scores

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San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Director, San Diego Branch

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San Diego Branch

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January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Individual Investigator Research Awards (IIRA), the Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), the Individual Investigator Research Awards for Clinical Translation (IIRACT), the Individual Investigator Research Awards for Computational Biology (IIRACB) and the Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on December 5, 2018 to consider the applications recommended by the peer review panels following their meetings that were held October 18, 2018 – October 25, 2018. Please note that RP190135 is included in the list below because it was recommended by the SRC; however, the application was subsequently withdrawn by the applicant.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The total amount for the applications recommended is $50,055,527.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	Application ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
1	RP190067	IIRACT	**1.1**	Improving T-Cell Therapy of Neuroblastoma With a Novel Cytokine Modulator: A Phase 1 Clinical Trial	Rooney, Cliona M	Baylor College of Medicine	$1,499,252
2	RP190417	IIRA	**1.2**	Decoding the Pathogenic Roles of Noncoding Variants in Hematopoietic Malignancies	Xu, Jian	The University of Texas Southwestern Medical Center	$900,000
3	RP190049	IIRACT	**1.2**	Noninvasive Detection and Assessment of Therapy Response in Multiple Myeloma Using Whole-Body MRI	Madhuranthakam, Ananth J	The University of Texas Southwestern Medical Center	$1,189,577
4	RP190451	IIRA	**1.3**	Comprehensive Evaluation of Functional Enhancers in Breast Cancer Risk Susceptibility Loci	Hon, Gary C	The University of Texas Southwestern Medical Center	$896,892
5	RP190022	IIRAP	**1.4**	A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses Versus 3 Doses of the 9-Valent HPV Vaccine in Males and Females 15 to 26 Years of Age	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,491,473
6	RP190207	IIRA	**1.9**	Understanding the Role of FBXW7 as a Defining Driver of Uterine Carcinosarcoma	Castrillon, Diego H	The University of Texas Southwestern Medical Center	$881,433
7	RP190012	IIRA	**1.9**	Berberine in Prevention of Biochemical Recurrence	Kumar, Addanki P	The University of Texas Health Science Center at San Antonio	$900,000
8	RP190135	IIRACT	**1.9**	Preventing Chemoradiation Bone Marrow Toxicities With FLT PET and SOD Mimics	McGuire, Sarah	The University of Texas Southwestern Medical Center	$2,087,928*
9	RP190400	IIRACCA	**1.9**	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction in Childhood Cancer Survivors	Noel, Cory V	Baylor College of Medicine	$1,192,412
10	RP190043	IIRA	**2.0**	Mitochondrial Metabolism and RNA Methylation in Cancer	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	$900,000

11	RP190398	IIRA	**2.0**	Targeting the Mechanism of Hyperactive FOXA1 in Transcriptional Reprogramming Toward Endocrine Resistance and Metastasis in Breast Cancer	Schiff, Rachel	Baylor College of Medicine	$899,566
12	RP190019	IIRA	**2.0**	Lymphatic Delivery of Checkpoint Blockade Inhibitors for More Effective Immunotherapy	Sevick, Eva M	The University of Texas Health Science Center at Houston	$900,000
13	RP190278	IIRA	**2.0**	Investigating Brain Tumor Drug Delivery by Optical Modulation of Blood-Brain Barrier Using Plasmonic Nanobubbles	Qin, Zhenpeng	The University of Texas at Dallas	$900,000
14	RP190192	IIRA	**2.1**	Pharmacological Targeting of the IRE1/XBP1 Pathway for Triple-Negative Breast Cancer Therapy	Koong, Albert	The University of Texas M. D. Anderson Cancer Center	$900,000
15	RP190236	IIRA	**2.1**	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,397
16	RP190279	IIRAP	**2.2**	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)–Mediated Lung Carcinogenesis by Omega-3 Fatty Acids	Moorthy, Bhagavatula	Baylor College of Medicine	$899,151
17	RP190160	IIRACT	**2.2**	Interleukin-15– and -21–Armored Glypican-3–Specific CAR T Cells for Patients With Hepatocellular Carcinoma	Heczey, Andras	Baylor College of Medicine	$2,400,000
18	RP190107	IIRACB	**2.3**	Digital Pathology Analysis for Lung Cancer Patient Care	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$885,185
19	RP190256	IIRA	**2.4**	Role of S1PR1 in Exercise-Induced Tumor Vascular Remodeling	Schadler, Keri	The University of Texas M. D. Anderson Cancer Center	$899,992

20	RP190301	IIRA	2.4	Biophysical Mechanisms of Human Microhomology-Mediated End Joining	Finkelstein, Ilya J	The University of Texas at Austin	$900,000
21	RP190077	IIRA	2.4	Molecular Action of Phospho-BRD4–Targeting Compounds in Breast Cancer	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	$864,000**
22	RP190435	IIRA	2.4	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress	Sadek, Hesham	The University of Texas Southwestern Medical Center	$900,000
23	RP190295	IIRA	2.4	Targeting Hypomethylating Resistance in Myelodysplastic Syndromes	Colla, Simona	The University of Texas M. D. Anderson Cancer Center	$900,000***
24	RP190326	IIRA	2.4	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	$900,000
25	RP190218	IIRA	2.5	Deciphering the Underlying Biology and Translational Relevance of PD-L2	Curran, Michael A	The University of Texas M. D. Anderson Cancer Center	$900,000
26	RP190252	IIRA	2.5	A Novel Therapy Targeting Prostate Cancer–Induced Aberrant Bone Formation	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$900,000
27	RP190210	IIRAP	2.5	Improving the Quality of Smoking Cessation and Shared Decision-Making for Lung Cancer Screening: A Cluster Randomized Trial	Volk, Robert J	The University of Texas M. D. Anderson Cancer Center	$1,499,527
28	RP190132	IIRACCA	2.5	Multiomic Biomarker Discovery for Therapy-Related Neurocognitive Impairment in Childhood Acute Lymphoblastic Leukemia	Brown, Austin L	Baylor College of Medicine	$1,187,006
29	RP190385	IIRACCA	2.6	Growth Signaling in Ewing Sarcoma	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	$1,200,000
30	RP190360	IIRACT	2.6	Immunotherapeutic Targeting of SLC45A2 for Treatment of Uveal Melanoma	Yee, Cassian	The University of Texas M. D. Anderson Cancer Center	$2,399,991
31	RP190029	IIRA	2.7	The EZH2 Deubiquitinase ZRANB1 as a Therapeutic Target in Breast Cancer	Ma, Li	The University of Texas M. D. Anderson Cancer Center	$900,000

32	RP190131	IIRA	2.7	Neoadjuvant Treatment Response Monitoring of Breast Cancer With Molecular Photoacoustic Imaging	Bouchard, Richard	The University of Texas M. D. Anderson Cancer Center	$895,907
33	RP190235	IIRA	2.8	Role of Long Noncoding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	Kraus, W. Lee	The University of Texas Southwestern Medical Center	$899,747
34	RP190002	IIRACCA	2.8	Development of a Precision Drug to Target STAG2 (SA2)–Mutant Ewing Sarcoma	Pati, Debananda	Baylor College of Medicine	$1,189,218
35	RP190233	IIRACCA	2.8	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leukemia Using Translatable Nanotechnology	Lux, Jacques	The University of Texas Southwestern Medical Center	$1,200,000
36	RP190454	IIRA	2.9	Characterization of CTCF-Mediated 3D Genome Organization and Transcriptional Regulation in Metastatic Prostate Cancer	Mani, Ram S	The University of Texas Southwestern Medical Center	$900,000
37	RP190211	IIRA	2.9	Assessments of Tumor Perfusion With Dynamic Contrast–Enhanced Multispectral Optoacoustic Tomography	Pagel, Mark D	The University of Texas M. D. Anderson Cancer Center	$886,927
38	RP190251	IIRA	3.0	Defining and Enabling Delivery of microRNA and CRISPR Therapeutics for Hepatocellular Carcinoma (HCC)	Siegwart, Daniel J	The University of Texas Southwestern Medical Center	$900,000
39	RP190414	IIRACCA	3.1	Biochemical and Genetic Interrogation of EWSR1-FLI1 in Ewing Sarcoma	McFadden, David G	The University of Texas Southwestern Medical Center	$1,200,000
40	RP190287	IIRA	3.1	Regulation of CD8 T-Cell Responses in Antitumor Immunity	Sun, Shao-Cong	The University of Texas M. D. Anderson Cancer Center	$900,000
41	RP190421	IIRA	3.1	Structure-Based Drug Design of Inhibitors for a Breast Cancer Signature Kinase	Goldsmith, Elizabeth J	The University of Texas Southwestern Medical Center	$900,000
42	RP190346	IIRACB	3.3	Predicting Drug Response From Genomic Data Using Deep Learning Methods	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$892,157

43	RP190366	IIRA	**3.3**	Characterization and Optimization of Novel Allosteric KRAS Inhibitors	Gorfe, Alemayehu A	The University of Texas Health Science Center at Houston	$897,483
44	RP190208	IIRACB	**3.4**	Dissecting Cellular Heterogeneity of Bulk Tumors for Prediction of Overall Survival and Responsive Patients to Immunotherapy	Wang, Tao	The University of Texas Southwestern Medical Center	$900,000
45	RP190401	IIRACCA	**3.4**	A Mouse Model for Studying DIPG Initiation and Progression in the Pons	Xie, Zhigang	Texas A&M University System Health Science Center	$721,306
46	RP190358	IIRA	**3.4**	The Role of ZMYND8 in Breast Cancer Stem Cells and Tumor Progression	Luo, Weibo	The University of Texas Southwestern Medical Center	$900,000
47	RP190259	IIRA	**3.4**	Role of the N6-Methyladenosine (m6A) Writer METTL3/METTL14 in Cancer	Nam, Yunsun	The University of Texas Southwestern Medical Center	$900,000

*RP190135 – PI withdrew application POST- SRC recommendation and PRE-PIC meeting
**RP190077 reflects budget as reduced by the SRC. SRC recommended the removal of the 3rd aim.
*** RP190295 SRC recommended requiring 10% effort for PI in order to fund.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Company Relocation Product Development Awards

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA C-19.1-RELCO

Company Relocation Product Development Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on May 29, 2018

Application Receipt Opening Date: June 28, 2018

Application Receipt Closing Date: August 8, 2018

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 5/17/2018 RFA release

Rev 05/29/2018 RFA was revised (section 8.1, p. 10) informing applicants to submit only one Product Development Research application per cycle.

1. KEY POINTS

This Company Relocation Product Development Research Award mechanism is governed by the following restrictions:

- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools.
- For therapeutics, Product Development Research award funding supports preclinical research and early clinical research necessary to demonstrate initial clinical safety and efficacy (typically phase 1, phase 2A).
- Recipient companies must commit to be Texas based (see section 8.1). The Cancer Prevention and Research Institute of Texas (CPRIT) requires the use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities.
- CPRIT requires recipient companies to raise a portion of the total project budget from external sources. For a company receiving an initial CPRIT award, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the recipient company. CPRIT reserves the right to seek a higher matching funds contribution (ie, CPRIT will contribute $1.00 for every $1.00 contributed in matching funds by the company) from a company that has already received a CPRIT award and is approved for a second award. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds should, whenever possible, be spent in Texas. A company's matching funds must be dedicated to the CPRIT-funded project but may be spent outside of Texas.
- Applicants may request up to $20 million in CPRIT funds. CPRIT receives many more applications each year than available funds can support. While all requests for funding must be well justified, a funding request at or near the maximum amount will be heavily scrutinized. Such a request must be exceptionally well justified to warrant dedicating a large percentage of CPRIT's product development research budget to the applicant's project.
- Funding will be tranched and tied to the achievement of contract-specified milestones.
- All award contracts include a revenue-sharing agreement. **A copy of the revenue-sharing agreement can be found at www.cprit.texas.gov in the Product Development**

Research Program section. Other contract provisions are specified in CPRIT's Administrative Rules, which are also available at www.cprit.texas.gov.

- An application last submitted but not funded (including resubmission) before June 28, 2016, may be submitted as a new application, even if it was previously resubmitted (see section 8.2).

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Research Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Product Development Research Program's principles and priorities will also guide CPRIT staff and the Product Development Review Council on the development and issuance of

program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of patients with cancer
- Creation of good, high-paying jobs for Texans
- Sound financial return on the monies invested
- Development of the Texas high-tech life sciences business environment

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available; ie, disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early-stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff, to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

A full description of CPRIT's program priorities may be found at http://www.cprit.texas.gov/about-cprit/reports/.

3. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. The award mechanism described in this RFA is designed to encourage the relocation of existing oncology-focused companies or a substantial portion of their business to Texas. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology,

causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by increasing the availability of Food and Drug Administration (FDA)–approved therapeutic interventions with a primary focus on Texas-centric programs.

4. MECHANISM OF SUPPORT

The goal of the Company Relocation Product Development Research Award is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will provide companies or limited partnerships that are willing to relocate all or a substantial portion of their business to Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

5. OBJECTIVES

The State of Texas seeks to attract industry partners in the field of cancer care to advance economic development and cancer care efforts in the state. The goal of this award mechanism is to recruit to Texas companies with proven management teams who are focused on exceptional product opportunities to improve cancer care. These companies must presently be domiciled outside of Texas and have sufficient personnel to operate the Texas-based research and/or development activities of the company and, along with appropriate management, must be willing to relocate to or be hired and remain in Texas for a specified period after funding.

The long-term objective of this award is to support commercially oriented therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA should be the intent to further the research and development of products that would eventually be approved and marketed for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques.

CPRIT seeks to maximize the clinical impact of our funding. Hence, we focus investment in translational research and development activities, including the following eligible stages:

- Studies that establish preclinical proof of concept;
- GLP studies to support INDs;
- Phase 1 to establish safety and a maximally tolerated dose;
- Phase 2 studies to determine safety and efficacy in initial targeted patient populations (up to 100 patients).

CPRIT typically does not fund efforts outside of these parameters. We do not consider studies larger than what are described as "translational" and, hence, such studies are outside the scope of our interest. Companies that have clinically demonstrated safety and efficacy should be able to acquire necessary capital via other sources. By exception, later clinical trials or later-stage product development projects may be considered where exceptional circumstances warrant CPRIT investment.

CPRIT's objectives and program priorities are established by its Oversight Committee. Consistent with the above, these priorities include, "funding projects at Texas companies and relocating companies that are most likely to bring important products to the market." A full description of CPRIT's program priorities may be found at http://www.cprit.texas.gov/about-cprit/reports/.

6. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development project proposed. Requested funds must be well justified. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property (IP) protection, external consultants and service providers, travel in support of the project, and other appropriate research and development costs, subject to certain limitations set forth by Texas law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state. Texas law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

For companies receiving an initial CPRIT award, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the company. CPRIT reserves the right to seek a higher matching funds contribution, ie, CPRIT will contribute $1.00 for every $1.00 contributed in matching funds by the company, from a company that has already received a CPRIT award and is approved for a second award. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be fulfilled on a year-by-year basis.

7. KEY DATES

RFA release	May 17, 2018
Online application opens	June 28, 2018, 7 AM central time
Applications due	August 8, 2018, 4 PM central time
Invitations to present sent	October 2018
Notifications sent if not invited	October 2018
Presentations to CPRIT*	October 2018
Award Notification	February 2019
Anticipated Start Date	March 2019

* Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

8. ELIGIBILITY

8.1. Applicants

- Applicants may be located outside the State of Texas when the application is submitted and reviewed. However, CPRIT requires the grant applicant to demonstrate that it will relocate to Texas as a condition of the grant award. A company is considered to be Texas based if it currently fulfills or commits to fulfilling a majority of the following criteria:

    1. The US headquarters is physically located in Texas.

    2. The Chief Executive Officer resides in Texas.

    3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.

4. Manufacturing activities take place in Texas.
5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
6. At least 1 clinical trial site is in Texas.
7. The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

Companies are typically required to meet the first 3 criteria. CPRIT recognizes meeting each of criteria 4 through 7 may not always be feasible. Hence, CPRIT may afford flexibility with these requirements, in specific circumstances, provided a majority of criteria are met. In exceptional circumstances, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

Unless otherwise specified by the award contract, all location requirements identified by the applicant must be fulfilled within 1 year of receiving the initial disbursement of funds. Failure to maintain compliance with the location criteria will result in consequences ranging from suspension of grant funding to early termination of the grant contract and repayment of grant funds.

- An applicant may submit only 1 application under this RFA during this funding cycle.
- An application last submitted (including resubmissions) before June 28, 2016 may be submitted as a new application, even if it was previously resubmitted.
- Please note that in any given application round, applicants will typically only be allowed to apply for <u>one</u> Product Development award (TXCO, RELCO or Seed) at a time. Applicants are advised to review each RFA and select the program that best fits their development status.
- Only 1 coapplicant may be included on the application. For the Product Development Research Program, a coapplicant is an individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, coapplicants share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple applicants are named, each is

responsible and accountable for the proper conduct of the project, program, or activity, including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.

- A company applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individual within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- A company applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The company applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or other individuals are ineligible to receive federal grant funds or have had a grant terminated for cause, the applicant may be contacted to provide more information.
- CPRIT grants will be awarded by contract to successful company applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the company applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

8.2. Resubmission Policy

- An application previously submitted to CPRIT within the last 2 years (after June 28, 2016) but not funded may be resubmitted once and must follow all resubmission guidelines (see section 10.4.6). **An application that was last submitted (including a resubmission to CPRIT) before June 28, 2016, may be submitted as a new application, even if the most recent submittal prior to June 28, 2016, was a resubmission.** It is expected that significant progress will have been made on the project; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to submit an application with such modest changes.
- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. An application that was administratively withdrawn by the applicant or by CPRIT prior to review by the review panel is not considered a submission for purposes of CPRIT's resubmission policy.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received an overall numerical score of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9. APPLICATION REVIEW

9.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. In general, a greater extent of commitment to establishing research and/or development functions in Texas will be viewed more favorably by CPRIT. However, it is left to the applicant's judgment to make a case for what they consider to be a sufficient extent of commitment to Texas.

CPRIT requires the submission of a comprehensive development plan (see section 10.4.7) and a detailed business plan (see section 10.4.8). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and development plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made via the review process described below.

9.2. Review Process

- **Product Development and Scientific Review:** Applications that pass initial administrative review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of company applicants may be invited to deliver in-person presentations to the review panel.
- **Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—IP, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications may be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and IP reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.

- **Program Integration Committee Review:** Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.
- **Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Any form of communication regarding any aspect of a pending application is prohibited between the company applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that

the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

Attached to this RFA is a list of more detailed questions considered by CPRIT reviewers when assessing therapeutic applications (Appendix 1, "Reviewer Evaluation Guidelines for Therapeutics") and when assessing medical medical devices, diagnostics, and/or tools (Appendix 2, "Reviewer Evaluations Guidelines for Medical Devices and Diagnostics"). Applicants are encouraged to review these documents and, to the extent possible, address the questions within their application.

9.3.1. Primary Criteria

Primary review criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study.

The criteria provided below are designed to provide an **overview** of topics that may be pertinent to the assessment of applications during peer review. Specific criteria applied to evaluate a given application will depend on the type of product described by the applicant (eg therapeutic versus medical device). **Detailed descriptions of the specific criteria employed for different product classes are provided in the appendices to this RFA.**

Primary review criteria are heavily weighted in determining the quality of an application. Reviewers provide numerical scores for these topic areas when evaluating applications. Primary criteria are intended to address the following topics:

Significance and Impact: Will the outcomes of this CPRIT-funded project result in the development of innovative products with significant product development potential? Will the intended product significantly address an unmet medical need, either in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?

Market Plan: Is there a realistic assessment of the market size and expected penetration? Has the applicant addressed patients, market segments, value proposition, pricing, outcomes research, sales plans, marketing research plans, or results? If the applicant plans to seek acquisition by a strategic partner, is there a well-characterized analysis of exit strategy and valuation? Is there an appropriate basis for a reimbursement strategy? Considering the initial clinical indications for the product, its competitive strengths/weaknesses and pricing/reimbursement objectives, are market/segment penetration and sales/profitability projections reasonable?

Clinical/Regulatory Plan: Is the clinical and regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both positive and negative outcomes? Does the budget appropriately support the plan? Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions, eg, United States/European Union? Do development proposals reflect specific regulatory authority input?

Competitive Landscape: Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the product compared to clinically relevant, competitive products, including potentially competitive agents in development? Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable?

Intellectual Property: Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP? Are there opportunities for meaningful patent life extension? Has the applicant secured appropriate licenses conferring freedom to operate?

Development Plan: Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date? Will the proposed programs

advance development of the product to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding? Are development milestones clear and adequately described? Is the overall project timeline realistic? Are potential research and developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy? Does the applicant have the necessary experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and manufacturing? Does the team have access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan? If not, are there plans to address such deficiencies?

Financial Plan: Is there a comprehensive analysis of the aggregate funding required to market or exit and strategy to raise the required funding? If the applicant needs to raise further funds for the CPRIT matching requirement, how realistic are their assumptions about a successful fund-raising campaign? Do the development milestones and expected results of the research program reasonably support such assumptions? Has the applicant demonstrated that the returns are sufficient to justify the investment on a risk-adjusted basis?

Production/Manufacturing: How advanced is production/manufacturing development? Are there any sourcing issues? Has the applicant demonstrated that the product can be manufactured at commercial scale and with a reasonable cost? Are there significant technical difficulties still to be addressed?

9.3.2. Secondary Criteria

Secondary review criteria contribute to the global score assigned to the application and are not assigned individual numerical scores. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

Budget and Duration of Support: Are the budget and duration of support appropriate and realistic for the proposed project? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is there sufficient clarity in the budget proposal as to how funds will be

expended? Is there sufficient clarity in the budget proposal as to the spending of funds in Texas? Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

10. SUBMISSION GUIDELINES

Applicants are advised to review carefully all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available on May 29, 2018. Applications that are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

10.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The company applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the company applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. It is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires that the applicant and the ASO have 2 different accounts and user names. Applications will be accepted beginning at 7 AM central time on June 28, 2018, and must be submitted by 4 PM central time on August 8, 2018. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.2. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. Late submissions are permitted only in exceptional instances, usually for technology failures in the CARS. It is imperative that applicants allow sufficient time to familiarize themselves with the application

format and instructions to avoid unexpected issues. The applicant's failure to adequately plan is not sufficient grounds to justify approval of a late submission.

Peer review schedules are set far in advance and do not accommodate receipt of an application days after the deadline. Therefore, potential applicants that are unable to meet the deadline due to issues such as travel, sabbaticals, conferences, prolonged illness, or other leave, etc, should not request additional time to submit an application but should instead consider submitting the application in the next review cycle.

A request to extend the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

10.3. Product Development Review Fee

All applicants must submit a nonrefundable fee of $1,000 for review of Product Development Research applications. Payment should be made by check or money order payable to Cancer Prevention and Research Institute of Texas; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit a late fee has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed to the following address:

Cancer Prevention and Research Institute of Texas
Travis State Office Building
1701 N Congress Ave Ste 6-127
Austin, Texas 78701

Contact Name: Michelle Huddleston

Phone 1-512-305-8420

10.4. Application Components

Applicants are advised to minimize repetition among application components to the extent possible. In addition, applicants should use discretion in cross-referencing sections in order to maximize the amount of information presented within the page limits.

Please note that letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc, are **not** required or requested. If applicants choose to include such

letters, they may only be added to the Development or Budget Plan sections and will count toward the page limit for that section.

10.4.1. Layperson's Summary (1,500-character maximum)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The layperson's summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

10.4.2. Slide Presentation (10-page maximum)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with 1 slide filling each landscape-orientated page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.4.3. Abstract and Significance (5,000-character maximum)

Coherently explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Address how the proposed project, if successful, will have a major impact on the care of patients with cancer. Describe how this application provides a path for acquiring proof-of-principle data necessary for next-stage commercial development. Clearly explain the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.4.4. Goals and Objectives (maximum of 1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. Identify time-specific references as follows: Year 1, Quarter 1 (Y1Q1), Y1Q2, etc. Do not specify actual calendar dates as this can be confusing when dates change.

10.4.5. Timeline (1-page maximum)

Provide a visual depiction of anticipated major milestones to be tracked in the form of a Gantt chart. Identify time-specific references as follows: Y1Q1, Y1Q2, etc, as opposed to naming specific months and years. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

10.4.6. Resubmission Summary (1-page maximum)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application submitted or resubmitted before June 28, 2016, may be submitted as a new application, even if it was previously resubmitted. For the "new" applications, no summary is required.

10.4.7. Development Plan (12-page maximum)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. **Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims**. Outline the steps to be taken during the proposed period of the award, including the design of the translational and/or clinical

research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches to these risks. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The development plan should include a defined **target product profile (TPP)** or analogous document for a medical device, in vitro diagnostic, or service that projects a clear path to full commercialization (see http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm080593.pdf). The TPP provides a statement of the *overall intent* of the product development program and gives information about the product *at a particular time* in development. Usually, the TPP is organized according to the key sections in the product package insert for a drug or biologic or medical device labeling and links development activities to specific concepts intended for inclusion in the product labeling. CPRIT recognizes that many applications are early in the development process and that not all elements of the TPP will be known at the time of application. Consequently, not only does the TPP serve as a snapshot in time of the development status of the program, but it additionally serves as an aspirational target upon eventual commercialization. The TPP should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, medical device, diagnostic, or service that could be useful in the treatment of cancer?
- Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
- Description of a high-level clinical development plan detailing each of the clinical studies supporting marketing approval (phase 1, 2, and 3) the preclinical work is meant to support. Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the phase 1, phase 2, and phase 3 studies necessary to obtain regulatory approval

and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Applicants developing cancer therapeutics are encouraged to become familiar with FDA guidance documents for submission of applications related to new product development. These documents provide a standard framework for new drug submissions and biologic license applications to the FDA. Utilizing this framework helps ensure that the submission to CPRIT contains all relevant elements and is optimally organized.

Additionally, for therapeutics, the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or will the use of this new agent require a paradigm shift (more frequent or less frequent dosing, new route or method of administration), and if so, what impact will it have on current standard of care?

Optimization of the lead to ensure desired characteristics, including, but not limited to, the following studies:

- Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced
- Absorption, distribution, metabolism, excretion, including, but not limited to, relevant studies based on route of administration
- Safety (studies as mandated by ICH guidelines)
- Biomarkers (assays) that potentially target specific patient populations for clinical trials
- Biomarkers (assays) that can serve as potential pharmacodynamic markers of clinical activity during early clinical trials designed to demonstrate proof of concept
- Proposed current good manufacturing practice (including estimated costs) that can be scalable from phase 1 through phase 2. Include information on whether there are plans for possible formulation.

The FDA's website provides "Common Technical Documents" (CTDs, see http://www.ich.org/products/ctd.html) guidance documents. There are 3 CTDs covering safety, efficacy, and quality. This guidance presents a standard format for the preparation of a well-structured application. Applicants may condense or summarize the CTD format as they deem appropriate to meet page limitations.

While originally intended for regulatory authorities, these formats are also applicable for a CPRIT application. Many of our reviewers have extensive pharmaceutical development expertise and are familiar with these standard formats. Hence, utilizing the CTD format will simplify the review and ensure that the application contains all of the relevant elements.

CPRIT recognizes that many applications are early in the product development process. Hence, not all elements of the CTD will be known at time of CPRIT application. We encourage

applicants to complete as much of the Safety and Efficacy CTD sections as possible and to follow the submission format prescribed.

References for the Development Plan section should be provided as a stand-alone document that will be separately uploaded into CARS. In the interests of brevity include only the most pertinent and current literature. While references will not count toward the Development Plan section page limit, it is essential to be concise and to select only those references relevant to the development plan. **Do not use the references to circumvent Development Plan section page limits by including data analysis or other nonbibliographic material.**

The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. Please avoid redundancy!

10.4.8. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies typically need to raise substantial funds from private sources to fully fund development. Hence, we require companies to provide a business plan that summarizes the rationale for investing in this project. Private investors will seek a financial return on their investment. They will need to be convinced that this project has high investment return potential based on its risk profile. They typically focus on market opportunity size, development path, and key risk issues.

Successful applicants will provide thoughtful, careful, and succinct rationale explaining why this program is an appropriate investment of CPRIT and private funds. Note that if the company is selected to undergo due diligence, additional information to support the application will be requested at that time. Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

Please provide an overview of the business rationale for investing in this project. The business rationale overview will be 2 pages maximum. In addition, please provide summaries of the following 9 key development issues with a maximum of 1 page each.

1. **Product and Market:** Provide an overview of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc. Information on patient populations and market segments is helpful.
2. **Competition and Value Proposition:** Provide an overview of the competitive environment (current and future) and how the envisioned product will compete in the marketplace. Provide information on how the clinical utility (efficacy, safety, cost, etc) of this therapy compares with current and potential future therapies. A clear delineation of competitive advantages and data demonstrating these advantages are helpful.
3. **Clinical and Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities and the regulatory pathway for major markets. Please describe how this is driven by interactions with the FDA, if possible. The regulatory plan should include regulatory communications (including all interactions to date with the FDA) and strategy, with clarity provided on regulatory matters and current regulatory strategies.
4. **Pricing and Reimbursement:** Provide an overview of the product cost and anticipated revenue. Cost, price, and reimbursement references from similar products are helpful. An overview of how the company plans to obtain CMS and private insurance reimbursement approval is also helpful.
5. **Commercial Strategy:** Provide an overview of your financial projections and how you will generate a return on this investment. Describe how the company plans to bring the product to market. Information on physicians to be targeted, sales channels, etc, is helpful. Alternatively, many drugs are acquired by large pharma firms in the late development stages. If the company plans to seek acquisition, please provide an overview of similar transactions.
6. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated. Key risk issues typically include efficacy versus competitors, toxicity, clinical trials, FDA approval, dosage and delivery, CMC synthesis, changing competitive environment, etc.

7. **Funding to Date:** Provide an overview of the funding received, including a list of funding sources and a comprehensive capitalization table that should comprise all parties who have investments, stock, or rights in the company. A template exemplifying an appropriate capitalization table is provided among the application materials. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.
8. **Intellectual Property:** Provide a concise discussion of the IP issues related to the project. List any relevant issued patents and patent applications. Please include the titles and dates the patents were issued/filed/published. List any licensing agreements that the company has signed that are relevant to this application.
9. **Key Personnel Located in Texas and Any Key Management Located Outside of Texas:** For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, current geographic location (in particular, whether they are located within Texas) and any other information considered essential for evaluation of qualifications. Key personnel are the Principal Investigator/Project Director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way. *Substantive* means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. *Measurable* means that they devote a specified percentage of time to the project. The indicated time is an obligatory commitment, regardless of whether or not they request salaries or compensation. "Zero percent" effort or "TBD" or "as needed" are not acceptable levels of involvement for those designated as key personnel. While all participants that meet these criteria should be identified as "key," it is expected that the number of key personnel will be kept to a minimum.

The entire Business Plan section shall typically comprise a maximum of 11 pages: a 2-page overview and nine, 1-page key issue summaries. Please avoid redundancy. Note that the section "Funding to Date" above may exceed this 1-page limit if necessary.

10.4.9. Biographical Sketches of Key Scientific Personnel (8-page maximum)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. You may use the "Product Development Research Programs: Biographical Sketch" template but are not required to do so. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 10.4.8]).

10.4.10. Relocation Commitment to Texas (1-page maximum)

Provide a timetable with key dates indicating the applicant's plan and commitment to relocate the company to Texas. In addition, describe which personnel and management will be headquartered in Texas.

10.4.11. Budget

In preparing the requested budget, applicants should be aware of the following:

- Each award mechanism allows for up to a 3-year funding program with an opportunity for extension after the term expires. **The budget must be aligned with the proposed milestones.** Financial support will be awarded based upon the breadth and nature of the project proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.
- CPRIT considers equipment to be items having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. If awarded, management of your grant will be facilitated if specific equipment is clearly identified in the application using plain language. **Equipment not listed in the applicant's budget must be specifically approved by CPRIT subsequent to the award contract**.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.
- The total amount of CPRIT funds allowed for an annual salary of an individual for FY 2019 is $200,000. In other words, an individual may request salary proportional to the percent effort up to a maximum of $200,000. Salary amounts in excess of this limit must

be paid from matching funds. Salary does not include fringe benefits. CPRIT FY 2019 is from September 1, 2018, through August 31, 2019. Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of $200,000. The salary cap may be revised at CPRIT's discretion.

The Budget section is composed of 4 subtabs that must be completed:

A. **Budget for All Project Personnel:** Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project.

B. **Detailed Budget for Year 1:** <u>This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project</u>. Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Consultant Charges, Contractual (Subaward/Consortium), Research Related, or Other. Applicants will be required to itemize costs.

C. **Budget for Entire Proposed Period of Performance:** <u>This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project</u>. Provide the amount requested from CPRIT for direct costs for all subsequent years. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*.

D. **Budget Justification:** <u>Please specify your CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds</u>. Please specify each line item from your CPRIT budget as well as other funds (including matching funds). Provide a compelling justification for the budget for each line item of the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. **If travel costs will include out-of-state or international travel, make that clear here.** The budget must be aligned with the proposed milestones.

11. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and IP rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

Project Revenue Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement, which can be found at www.cprit.texas.gov and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has appropriate matching funds. For companies receiving an initial CPRIT award, the company must contribute $1.00 in matching funds for every $2.00 awarded by CPRIT. CPRIT reserves the right to seek a higher matching funds contribution, ie, the company will contribute $1.00 in matching funds for every $1.00 awarded by CPRIT, from a company that has already received a CPRIT award and is approved for a second award. Matching funds need not be in hand when the application is submitted, nor does the entire amount of matching funds for the full 3 years of the project need to be available at the start of the grant. However, the appropriate amount of matching funds for each specific tranche must be obtained before each tranche of CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. **Before contacting the helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. In addition, for Frequently Asked Programmatic Questions, please go here and for Frequently Asked Technical Questions, please go here.**

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146 (toll free in the United States only)
Email: Help@CPRITGrants.org

13.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Product Development Research Program Senior Manager.

Tel: 512-305-7676
Email: Help@CPRITGrants.org
Website: **www.cprit.texas.gov**

14. APPENDIX

14.1 Reviewer Evaluation Guidelines for Therapeutics

Primary Review Criteria (Scored)

Unmet medical need: Target Product Profile (TPP)

- Assuming successful accomplishment of development objectives, as reflected in the target product profile, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Target Validation

- If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
- Has engagement of the target with the agent been demonstrated by biochemical assay? What is the potency of the agent?
- Are there validated downstream pharmacodynamic (PD) markers of target modulation? How extensive is the in vitro evidence for expected PD effects? Has the agent shown biologically significant modulation of the target in vivo, especially in tumor tissue?
- Is the target uniquely or substantially overexpressed by tumor versus normal cells?
- Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
- Has the company's demonstration of target validation been externally/independently confirmed?
- Are there known mechanisms of resistance to the modulation of this target? If so, has the company proposed possible mitigation/preemptive approaches, such as combination chemotherapy?

Preclinical Characterization: Efficacy Proof of Concept

- Considering in vivo preclinical efficacy characterization and the patient populations or subpopulation(s) representing the initial clinical indication(s) for the drug, what is the

clinical relevance of the preclinical models? To elaborate, were in vivo/xenograft studies carried out in cell line-based models or PDX-derived models? In how many such models have studies been carried out? To what extent do these models reflect standard of care (SOC) for refractory versus drug-naive tumors? At the time of treatment initiation, were tumors established and measurable, or was treatment initiated shortly after tumor inoculation?

- Was antitumor activity predominantly growth inhibition or tumor regression? Were sustained complete remissions or "cures" achieved in the majority of animals and models? Were comparisons with optimally dosed SOC agents made? Where the agent is intended to be added to the SOC, is there compelling evidence of in vitro/in vivo synergy with SOC agents?
- Have results of preclinical efficacy studies carried out by the company been externally/independently confirmed?
- Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
- How strongly does the preclinical efficacy profile support the clinical efficacy expectations reflected in the TPP?

Preclinical Characterization: Safety

- How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
- Has the agent undergone CEREP-type screening for interactions with targets with known safety liabilities, eg, CYP 450, hERG?
- Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
- Can exposures associated with substantial antitumor efficacy/PD effects be achieved safely in vivo?
- Do preclinical pharmacokinetics (PK) studies indicate potential for clinical safety issues, eg, accumulation, variability, lack of dose proportionality?
- Have PK/PD issues been investigated with alternate dosing schedules in order to optimize the therapeutic index of the agent?
- Are there any issues with the distribution or metabolism of the agent?

- Overall, are results of safety characterization carried out so far such that the agent can be considered reasonably derisked from a safety perspective, or are there red flags? Alternatively, is the extent of preclinical safety characterization carried out so far insufficient to address this question?

Pharmaceutical Properties/Chemistry and Pharmacy

- In the case of agents intended for oral absorption, are there any issues with water solubility? Do formulation studies indicate the feasibility of oral administration?
- Were Lipinski-type criteria applied during the lead optimization process such that the lead compound has demonstrated properties that make it likely to be an orally active drug in humans?
- Are there any issues with the stability of the drug substance or the drug product?
- Is there scope for further lead optimization through structure activity studies?
- In the case of biologicals, has a high-quality cell line been developed yet? Are yields acceptable? Does the purification process appear reasonable and scalable?
- Have analytical methods been adequately developed?
- Has the (lead) protein been adequately characterized biochemically, immunogenetically, and biophysically? Has absence of aggregate formation been demonstrated in stability studies?

Development Plan/Regulatory Aspects

- Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
- Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions (United States/European Union)? Do development proposals reflect specific regulatory authority input, eg, from pre-IND interactions? Alternatively, has regulatory authority interaction been insufficient so far?
- In the case of clinical studies, are patient populations adequately described and consistent with those representing the initial target indication(s)?
- Are efficacy end points appropriate for study designs? Is the sample size statistically adequately justified in terms of the target effect size?

- In the case of potentially pivotal clinical trials, moreover, are the proposed primary efficacy end points and target effect sizes consistent with regulatory precedence?
- Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
- Has the applicant demonstrated reasonable diligence in researching patient availability, competitive clinical trial activity, and recruitment issues such that patient enrollment projections can be considered realistic?
- Will the proposed programs advance development of the agent to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding?
- Are development milestones clear and adequately described? Is the overall project timeline realistic?

Competitive Analysis

- Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the agent compared to clinically relevant competitive products, including potentially competitive agents in development?
- Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable, considering the preclinical efficacy and safety data on the agent generated so far?

Intellectual Property/Freedom to Operate

- Have IP and freedom-to-operate aspects been addressed in the application?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate?

Chemistry, Manufacturing, and Controls (CMC)

- How advanced is CMC and manufacturing development?
- Are there any sourcing issues?

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- Are there significant technical difficulties within CMC/manufacturing scale up still to be addressed?

Business/Commercial Aspects

- Does the applicant need to raise further funds for the CPRIT matching requirement? In this case, how realistic are the applicant's assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program of studies reasonably support such expectations?
- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and CMC/manufacturing? If not, are there plans to address such deficiencies?
- Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

14.2 Reviewer Evaluation Guidelines for Medical Devices and Diagnostics

Primary Review Criteria (Scored)

Product Validation

- Technical Validation: Has the product or technology been successfully validated, ie, prototyped, built and tested in ex vivo, animal, or clinical settings?
- Have biological proof of principle and product mechanism of action been demonstrated?
- Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
- Clinical Validation: Are clinical trials required to demonstrate product performance? If so, have they been planned or conducted?
- Biological Risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

Production/Manufacturing

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- How advanced is manufacturing development?
- Are there any sourcing issues?

Intellectual Property/Freedom to Operate

- Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique know-how, etc?
- Does the company have issued patents? If not, have they conducted freedom-to-operate and patentability analysis?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use), and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate, if required?

Market Opportunity

- Does the product address a clearly defined unmet need; lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?

- Are target indication and market clearly defined?
- Is channel to market available? Does the company understand the entire value chain and all constituencies involved in procuring and utilizing the product?
- Does the company understand the clinical pathway that leads to utilizing the product?
- Is market opportunity of significant size and lucrative enough to justify investment?
- Has the applicant demonstrated time or cost savings?
- How does product fit with the existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

Competition

- Is this a "Whole Product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
- Is value proposition clearly delineated, ie, improve efficacy, improve safety, reduce cost, or improve convenience?
- Has the company demonstrated its value proposition versus competition?
- Has the company conducted a competitive analysis? Does it provide a comprehensive, realistic assessment of strengths and weakness versus competition based on the data generated to date?

Development Plan

- Have a comprehensive development plan and market entry strategy been developed? How realistic are these plans?
- Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

Management and Staffing

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as product engineering, clinical development, regulatory affairs, manufacturing, etc? If not, are there plans to address such deficiencies?

- Has the applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Financial Plan

- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration, and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?
- Has the company clearly anticipated pricing strategy and reimbursement environment?
- Is the projected return on investment congruent with investment opportunity and risks?

Funding

- Is investor interest in this sector sufficient to fund the company through profitability?
- Does the applicant already have available funds to meet the CPRIT matching requirement, or do they need to raise additional funds? In this case, how realistic are assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Have likely acquirers been identified by the applicant?
- Does the company have the resources to support required activities while fundraising?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program reasonably support such expectations?

Secondary Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Does the applicant demonstrate an understanding of the Texas spending requirement for CPRIT funds?

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
2019 Cycle 1 19.1 Product Development Panel-1 Meeting
(19.1-PDR_PDP-1)
Observation Report

Report No.	09-24-18_19.1-PDR_PDP-1
Program Name:	Product Development Research
Panel Name:	2019 Cycle 1 19.1 Product Development Panel-1 Meeting (19.1-PDR_PDP-1)
Panel Date:	9/24/2018
Report Date:	9/26/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 2019 Cycle 1 19.1 Product Development Panel-1 meeting. The meeting was chaired by Jack Geltosky and conducted via teleconference on September 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observer(s) noted the following during the meeting:

- Number (#) of applications: 15 applications were discussed and 5 applications were not discussed
- Panelists: One (1) panel chair and Ten (10) expert reviewers and Two (2) advocate reviewers
- ICON employees: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to clarifying policies, and answering procedural questions

There were two (2) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

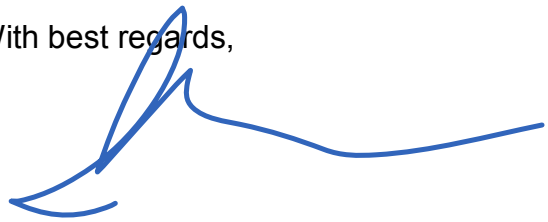
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
2019 Cycle 1 19.1 Product Development Panel-2 Meeting
(19.1-PDR_PDP-2)
Observation Report

Report No.	2018-09-25_19.1-PDR_PDP-2
Program Name:	Product Development Research
Panel Name:	2019 Cycle 1 19.1 Product Development Panel-2 Meeting (19.1-PDR_PDP-2)
Panel Date:	9/25/2018
Report Date:	9/27/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 2019 Cycle 1 19.1 Product Development Panel-2 meeting. The meeting was chaired by David Shoemaker and conducted via teleconference on September 25, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observer(s) noted the following during the meeting:

- Number (#) of applications: Eleven (11) applications were discussed and seven (7) were not discussed
- Panelists: One (1) panel chair and eleven (11) expert reviewers and two (2) advocate reviewers
- ICON employees: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

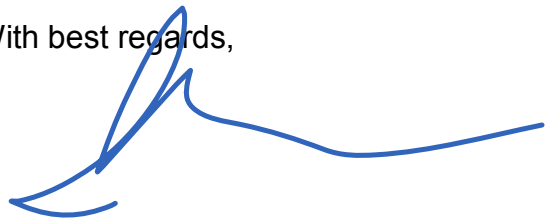
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Panel-1 Peer Review Meeting
(19.1_PDP-1)
Observation Report

Report No.	2018-10-23 19.1_PDP-1
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Panel-1 Peer Review Meeting (19.1_PDP-1)
Panel Date:	10-23/24-2018
Report Date:	10-30-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Panel-1 Peer Review (19.1_PDP-1) meeting. The meeting was chaired by Jack Geltosky and conducted via in-person in Dallas, Texas on October 23 and 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and Ten (10) were not discussed
- Panelists: One (1) panel chair and twelve (12) expert reviewers and two (2) advocate reviewers
- ICON employees: Two (2)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and four (4) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

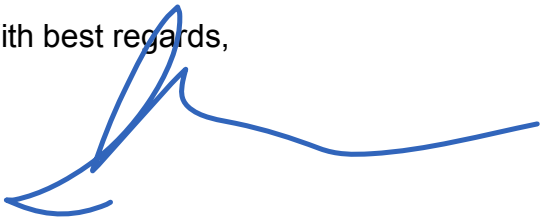
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Panel-2 Peer Review Meeting
(19.1_PDP-2)
Observation Report

Report No.	2018-10-25 19.1_PDP-2
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Panel-2 Peer Review Meeting (19.1_PDP-2)
Panel Date:	10-25/26-2018
Report Date:	10-30-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Panel-2 Peer Review (19.1_PDP-2) meeting. The meeting was chaired by David Shoemaker and conducted via in-person in Dallas, Texas on October 25 and 26, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and eleven (11) were not discussed
- Panelists: One (1) panel chair and fourteen (14) expert reviewers and two (2) advocate reviewers
- ICON employees: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

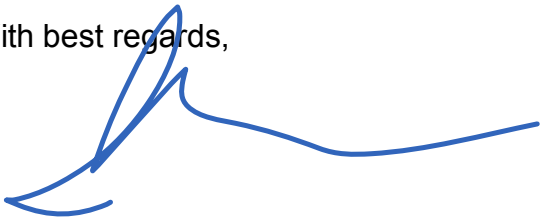
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part - 1 Meeting
(19.1_PDR_DD_P-1)
Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-1
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 1 Meeting (19.1_PDR_DD_P-1)
Panel Date:	01-11-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 1 Meeting (19.1_PDR_DD_P-1). The meeting did not have an assigned chair; the duties were performed by David Shoemaker and conducted via teleconference on January 11, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: Ten (10) expert reviewers
- ICON employees: Six (6)
- IP Attorneys: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

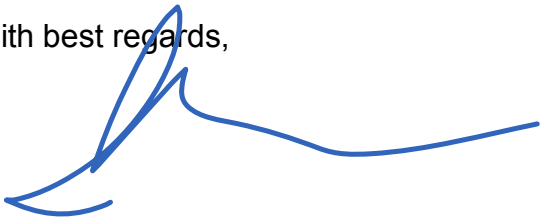
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part - 2 Meeting
(19.1_PDR_DD_P-2)
Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-2
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 2 Meeting (19.1_PDR_DD_P-2)
Panel Date:	01-14-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 2 Meeting (19.1_PDR_DD_P-2). The meeting did not have an assigned chair; the duties were performed by Jack Geltosky and conducted via teleconference on January 14, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: Eight (8) expert reviewers
- ICON employees: Six (6)
- IP Attorneys: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

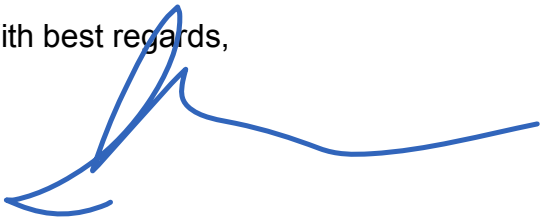
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part – 2 Continuation Meeting (19.1_PDR_DD_P-2 con.) Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-2 Continuation
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 2 Continuation Meeting (19.1_PDR_DD_P-2 Con.)
Panel Date:	01-22-2019
Report Date:	01-23-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 2 Continutation Meeting (19.1_PDR_DD_P-2 Con.). The meeting did not have an assigned chair; the duties were performed by Jack Geltosky and conducted via teleconference on January 22, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: Six (6) expert reviewers
- ICON employees: Zero (0)
- IP Attorneys: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

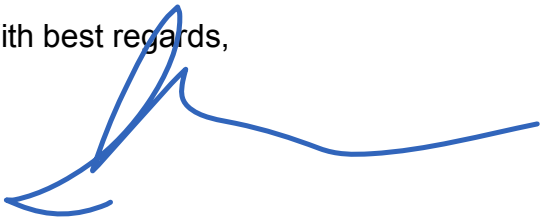
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



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Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Product Development Research Applications
(Product Development Research Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 19.1 include *Company Relocation Product Development Awards, Seed Awards for Product Development Research,* and *Texas Company Product Development Awards.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
DP190027	Piers Ingram	Hummingbird Bioscience Pte Ltd	V. Lee
DP190021	Kurt Gunter	Cell Medica	G. Williams;L. Greenberger
Applications not considered by the PIC or Oversight Committee			
DP190028	Laura Indolfi	PanTher Therapeutics, Inc	V. Lee
DP190035	Patrick Rivelli	Savran Technologies, Inc.	G. Cipau
DP190043*	Tania Fernandez	Midissia Therapeutics	H. Lyerly;V. Lee
DP190046	Mustapha Haddach	Pimera, Inc.	V. Lee
DP190047*	Sam Shrivastava	Venn Therapeutics, LLC	V. Lee
DP190060*	David Conway	Terra Biological LLC	V. Lee

High Level Summary of Due Diligence

RELCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommends that the Program Integration Committee and the Oversight Committee approve the following Relocation Company Product Development Research grant awards:

- Hummingbird Bioscience Pte. Ltd. for $13,116,095. No contract contingencies were recommended by the PDRC.

Hummingbird Bioscience Pte. Ltd.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Hummingbird Bioscience is developing a novel drug, HMBD-002, to reverse resistance to immune-oncology (IO) therapies. FDA-approved IO drugs harnessing the power of the body's immune system to fight cancer have made rapid advances in treating patients who previously had very few options. This includes patients with melanoma, non-small cell lung cancer, kidney and bladder cancer and several others. However, as many as 70% of these patients develop resistance and their cancer progresses, and they are again without options. The CPRIT project aims to bring a new cancer therapy to patients. The team will manufacture clinical-grade material and apply to the FDA for an Investigational New Drug application that will allow HMBD-002-V4 to begin a Phase IA/B study in Texas. The company intends to confirm in the proposed trial that the drug is safe and to start looking for responses from patients who have become resistant to approved IO therapies and whose cancers have progressed.

One reviewer summarized the significance and impact as follows: *If successful, the product will significantly address an unmet medical need. Patients that have disease refractory to current immunotherapy remain the largest percentage of those treated with IO therapy. That applies to the indications with highest patient numbers, including NSCLC, bladder, and renal cancer as proposed by the applicant. The majority of additional indications remains underserved. The applicant is proposing a reasonable approach to focus on this patient segment in which currently approved IO therapy fails and in tumor indications where IO therapy is approved.*

De-Identified Overall Evaluation Scores

Company Relocation Product Development Awards

Product Development Research Cycle 19.1

Application ID	Final Overall Evaluation Score
DP190027*	2.0
Ua**	2.5
Ub**	2.8
Uc	3.1
Ud	4.5
Ue	4.6
Uf	5.3
Ug	5.8
Uh	6.0

* Recommended for award

** The Product Development Review Council (PDRC) took no action on this application.

Final Overall Evaluation Scores and Rank Order Scores

January 23, 2019

Will Montgomery
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com
Via email to Will Montgomery's assistant, Laura Blevins, lblevins@jw.com

Wayne R. Roberts
Program Integration Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Will and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 19.1 grant award cycle.

The PDRC recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Hummingbird Bioscience, Allterum Therapeutics, Cell Medica, Icell Kealex Therapeutics and Instapath. The attached table reflects the ranked award recommendations, including the maximum recommended funding amounts and the overall evaluation scores for the five grant applications.

The PDRC did not make any changes to the goals, timelines, or budgets for the five projects recommended for funding. However, three of these recommendations are contingent on the review of the items described as follows:

- Execution of the CPRIT award contract for Allterum Therapeutics is contingent on the company's completion of the license agreement with the National Cancer Institute and CPRIT's review of documentation associated with the University of Maryland licensing agreement as outlined in the Vinson & Elkins IP Memorandum.
- Execution of the CPRIT award contract for Cell Medica is contingent on the company's completion of the recommendations set forth in the Vinson & Elkins IP Memorandum regarding patent coverage.
- Execution of the CPRIT award contract for Icell Kealex Therapeutics is contingent on resolution of the IP and licensing issues as outlined in the IP Diligence Memorandum from Baker Botts LLP.

The PDRC did not identify any contingencies associated with the awards to Hummingbird Bioscience or Instapath.

Each of companies included in the PDRC's recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PDRC's review of the due

diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

I will also note that the PDRC elected to take no action on two pending applications considered during due diligence review. Additional information is needed from the applicants before making final award decisions on DP190041 and DP190046. Once the applicants provide the requested information, the PDRC will reconvene and evaluate the data before making final award decisions. We anticipate that we will provide our award recommendations, if any, regarding these two pending proposals for consideration at either the May or August Oversight Committee meeting.

Sincerely,

/JG/ J Deltosky

Jack Geltosky, PhD

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations

FY 2019, Cycle 1

Rank	Application ID	Mech.	Company Name	Project	Maximum Recommended Budget	Overall Score
1	DP190027	RELCO	Hummingbird Bioscience Pte Ltd	A First-in-Class Anti-VISTA Monoclonal Antibody for the Treatment of MDSC-Mediated Suppression of Antitumor Immunity in Solid Tumors and Lymphomas	$13,116,095	2.0
2	DP190025	SEED	Allterum Therapeutics, LLC	Preclinical Development of a Novel T-ALL Therapeutic Antibody	$2,912,313	2.2
3	DP190020	SEED	Icell Kealex Therapeutics LLC	Development of a Novel Oncolytic Vaccinia Virus Variant Suitable for Systemic Delivery	$3,000,000	2.5
4	DP190021	TXCO	Cell Medica	Off-the-Shelf CAR-NKT Cells for Treatment of Solid and Hematological Malignancy	$8,742,509	3.1
5	DP190018	RELCO	Instapath Inc.	Rapid Pathology Evaluation System for Biopsies	$3,000,000	2.2
				Total	$30,770,917	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Seed Awards for Product Development Research

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA C-19.1-SEED

Seed Awards for Product Development Research

Please also refer to the Instructions for Applicants document, which will be posted on May 29, 2018

Application Receipt Opening Date: June 28, 2018

Application Receipt Closing Date: August 8, 2018

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 05/17/2018 RFA release

Rev 05/29/2018 RFA was revised (section 8.1, pp. 10-11) informing applicants to submit only one Product Development Research application per cycle.

1. KEY POINTS

This Seed Award for Product Development Research (Seed Award) mechanism is governed by the following restrictions:

- This new grant mechanism is open to company applicants to fund the development of therapeutics, devices, or tools designed to lessen the burden of cancer. The aim of the Seed Award is to narrow the funding gap (sometimes referred to as the "valley of death") between discovery and commercial development, with a focus on Texas-based oncology startups. All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools.
- In the case of therapeutics, Product Development Research award funding supports preclinical research that advances a project toward commercialization. Examples of typical drug development activities that are eligible for funding by this award include target validation studies, selection of a lead compound, validation of efficacy and safety in preclinical tests, and demonstration of manufacturability.
- Recipient companies must be Texas based (see section 8.1). If an applicant is not currently based in Texas, they must commit to relocating to Texas by meeting the Texas-based location criteria (see section 8.1) within 1 year of receiving the award. The Cancer Prevention and Research Institute of Texas (CPRIT) requires the use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities.
- CPRIT requires recipient companies to raise a portion of the total project budget from external sources. For a company receiving an initial CPRIT award, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the recipient company. CPRIT reserves the right to seek a higher matching funds contribution (ie, CPRIT will contribute $1.00 for every $1.00 contributed in matching funds by the company) from a company that has already received a CPRIT award and is approved for a second award. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds should, whenever possible, be spent in Texas. A company's matching funds must be dedicated to the CPRIT-funded project but may be spent outside of Texas.

- Applicants may request up to $3.0 million in CPRIT funds. Please note that CPRIT receives many more applications each year than available funds can support. Therefore, only the most meritorious applicants are awarded.
- Funding will be tranched and tied to the achievement of contract-specified milestones.
- All award contracts include a revenue-sharing agreement. **A copy of the revenue-sharing agreement can be found at www.cprit.texas.gov in the Product Development Research Program section.** Other contract provisions are specified in CPRIT's Administrative Rules, which are also available at www.cprit.texas.gov.
- Since this cycle is the first time CPRIT has offered the Seed Award, CPRIT considers all applicants to be first-time applicants. However, in future cycles CPRIT, plans to implement its resubmission policy limiting applicants to 1 resubmission. See section 8.2 for more details regarding the resubmission process.

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Research Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Product Development Research Program's principles and priorities will also guide CPRIT staff and the Product Development Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of patients with cancer
- Creation of good, high-paying jobs for Texans
- Sound financial return on the monies invested
- Development of the Texas high-tech life sciences business environment

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available; ie, disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early-stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff, to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

A full description of CPRIT's program priorities may be found at http://www.cprit.texas.gov/about-cprit/reports/.

3. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This RFA solicits applications for the research and development of innovative products addressing critically important needs related to diagnosis, prevention, and/or treatment of cancer and the product development infrastructure needed to support these efforts. CPRIT encourages applicants who seek to apply or develop state-of-the-art products, services (eg, contract research organization services), technologies, tools, and/or resources for cancer research, prevention, or treatment. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by increasing the availability of Food and Drug Administration (FDA)–approved therapeutic interventions with a primary focus on Texas-centric programs.

4. MECHANISM OF SUPPORT

CPRIT is initiating a new Seed Award for Product Development Research to support company formation and early development of novel oncology technologies. This new grant mechanism is open to company applicants to fund the development of therapeutics, devices, or tools designed to lessen the burden of cancer. The aim of the Seed Award is to narrow the funding gap (sometimes referred to as the "valley of death") between discovery and commercial development, with a focus on Texas-based oncology startups.

Seed Award investments provide companies or limited partnerships located and headquartered in Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

The Seed Award program provides product development funding to select early-stage companies and projects. Companies interested in this award will need to apply and undergo our application

review process. Seed Award applicants can request up to $3.0 million for projects of up to 3 years in duration.

5. OBJECTIVES

The long-term objective of this award is to support commercially oriented therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA should be the intent to further the research and development of products that would eventually be approved and marketed for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques.

The objective of the Seed Award program is to start with an interesting technology and to develop it into a commercially viable business opportunity, ie, make it more attractive to private funding agents. Typically, applicants have completed the following activities:

- Identified a novel therapeutic or diagnostic technology and shown a biological effect
- Replicated/verified the research in a second model and in a second lab
- Conducted preliminary safety and toxicology testing (in the case of therapeutic agents)
- Shown the product can be manufactured at small scale or as a prototype
- Assessed the business opportunity and organized a business plan that addresses key issues (clinical utility, target market, financial plan, IP strategy, technical challenges, etc) and development plan (formulation, toxicology, scale up, pre-IND development, clinical trials, regulatory pathway, etc).
- Initiated a patent application
- Established a company

6. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development project proposed. Requested funds must be well justified. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property (IP) protection, external consultants and service providers, travel in support of the project, and other appropriate research and development costs, subject to certain limitations set forth by Texas law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state. Texas law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

For companies receiving an initial CPRIT award, CPRIT will award $2.00 for every $1.00 contributed in matching funds by the company. CPRIT reserves the right to seek a higher matching funds contribution, ie, CPRIT will contribute $1.00 for every $1.00 contributed in matching funds by the company, from a company that has already received a CPRIT award and is approved for a second award. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be fulfilled on a year-by-year basis.

7. KEY DATES

RFA release	May 17, 2018
Online application opens	June 28, 2018, 7 AM central time
Applications due	August 8, 2018, 4 PM central time
Invitations to present sent	October 2018
Notifications sent if not invited	October 2018
Presentations to CPRIT*	October 2018
Award Notification	February 2019
Anticipated Start Date	March 2019

* Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

8. ELIGIBILITY

8.1. Applicants

- Recipient companies must be Texas based. A company is considered to be Texas based if it currently fulfills or commits to fulfilling a majority of the following criteria:

  1. The US headquarters are physically located in Texas.
  2. The Chief Executive Officer resides in Texas.
  3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.
  4. Manufacturing activities take place in Texas.
  5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
  6. At least 1 clinical trial site is in Texas.
  7. The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

  Companies are typically required to meet the first 3 criteria. CPRIT recognizes meeting each of criteria 4 through 7 may not always be feasible. Hence, CPRIT may afford flexibility with these requirements, in specific circumstances, provided a majority of criteria are met. In exceptional circumstances, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

  Unless otherwise specified by the award contract, all location requirements identified by the applicant must be fulfilled within 1 year of receiving the initial disbursement of funds. Failure to maintain compliance with the location criteria will result in consequences ranging from suspension of grant funding to early termination of the grant contract and repayment of grant funds.

- An applicant may submit only 1 application under this RFA during this funding cycle.
- Please note that in any given application round, applicants will typically only be allowed to apply for <u>one</u> Product Development award (TXCO, RELCO or Seed) at a time.

Applicants are advised to review each RFA and select the program that best fits their development status.

- Only 1 coapplicant may be included on the application. For the Product Development Research Program, a coapplicant is an individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, coapplicants share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple applicants are named, each is responsible and accountable for the proper conduct of the project, program, or activity, including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.
- A company applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individual within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- A company applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The company applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or other individuals are ineligible to receive federal grant funds or have had a grant terminated for cause, the applicant may be contacted to provide more information.
- CPRIT grants will be awarded by contract to successful company applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the company applicant need not demonstrate the ability to comply with these contractual

requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

8.2. Resubmission Policy

Since this is the first application cycle for the Seed Award, CPRIT considers all applicants in this cycle to be first-time applicants. In future cycles, CPRIT plans to implement the following resubmission policy:

- An application previously submitted to CPRIT within the last 2 years but not funded may be resubmitted once and must follow all resubmission guidelines. It is expected that significant progress will have been made on the project; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to submit an application with such modest changes.
- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. An application that was administratively withdrawn by the applicant or by CPRIT prior to review by the review panel is not considered a submission for purposes of CPRIT's resubmission policy.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received an overall numerical score of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not**

guarantee the success of the resubmission. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9. APPLICATION REVIEW

9.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT requires the submission of a comprehensive development plan (see section 10.4.6) and a detailed business plan (see section 10.4.7). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and development plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made via the review process described below.

9.2. Review Process

- **Product Development and Scientific Review:** Applications that pass initial administrative review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of company applicants may be invited to deliver in-person presentations to the review panel.
- **Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—IP, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications may be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and IP reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.
- **Program Integration Committee Review:** Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration

Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.

- **Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Any form of communication regarding any aspect of a pending application is prohibited between the company applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of

State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

Attached to this RFA is a list of more detailed questions considered by CPRIT reviewers when assessing therapeutic applications (Appendix 1, "Reviewer Evaluation Guidelines for Therapeutics") and when assessing medical devices, diagnostics and/or tools (Appendix 2, "Reviewer Evaluations Guidelines for Medical Devices and Diagnostics"). Applicants are encouraged to review these documents and, to the extent possible, address the questions within their application.

CPRIT recognizes much, if not most, of this information is not available at this stage of development. We encourage applicants to be as thorough as possible in describing their current stage of development.

9.3.1. Primary Criteria

The objective of a Seed Award is to fund the work necessary to select a drug candidate (or, in the case of diagnostics/tools, to complete validation work) and position the company to raise private capital. As an example, in the case of drug candidates, specific technical activities the Seed Award mechanism can fund may include:

- Perform target validation
- Conduct lead optimization
- Perform target and cellular potency studies

- Explore activity in xenograft models and determine pharmacokinetics and exposure; test whether concentrations that result in significant cell death in vitro can be safely achieved in vivo
- Evaluate biopharmaceutical properties (absorption in rodents and nonrodents, clearance, and bioavailability)
- Optimize synthetic/bioengineering route
- Develop prototype clinical formulation
- Expand preclinical safety characterization; perform pharmacokinetic and pharmacodynamic assessments
- Evaluate biodistribution

Seed Awards may be used to carry out comparable activities for other classes of applications such as medical devices or diagnostics.

Specific business activities the Seed Award mechanism can fund may include the following:

- Competitive analysis
- Business opportunity assessment
- Target Product Profile development
- Organization of development plan
- Commercial strategy development including assessing potential pitfalls and alternatives
- Definition of competitive safety and efficacy thresholds vis-à-vis competition
- Preparation of clinical development plan
- IP development

Primary review criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study.

The criteria provided below are designed to provide an **overview** of topics that may be pertinent to the assessment of applications during peer review. Specific criteria applied to evaluate a given application will depend on the type of product described by the applicant, eg, therapeutic versus medical device. **Detailed descriptions of the specific criteria employed for different product classes are provided in the appendices to this RFA.**

Primary review criteria are heavily weighted in determining the quality of an application. Reviewers provide numerical scores for these topic areas when evaluating applications. Primary criteria are intended to address the following topics:

Significance and Impact: Will the outcomes of this CPRIT-funded project result in the development of innovative products with significant product development potential? Will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?

Market Plan: Is there a realistic assessment of the market size and expected penetration? Has the applicant addressed patients, market segments, value proposition, pricing, outcomes research, sales plans, marketing research plans, or results? If the applicant plans to seek acquisition by a strategic partner, is there a well-characterized analysis of exit strategy and valuation? Is there an appropriate basis for a reimbursement strategy? Considering the initial clinical indications for the product, its competitive strengths/weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales/profitability projections reasonable?

Clinical/Regulatory Plan: Is the clinical and regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both positive and negative outcomes? Does the budget appropriately support the plan? Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions, eg, United States/European Union? Do development proposals reflect specific regulatory authority input?

Competitive Landscape: Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the product compared to clinically relevant, competitive products, including potentially competitive agents in development? Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable?

Intellectual Property: Considering patent type (Composition of Matter/Formulation/ Manufacturing Process/Use) and duration of patent life, how strong is the IP?

Are there opportunities for meaningful patent life extension? Has the applicant secured appropriate licenses conferring freedom to operate?

Development Plan: Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date? Will the proposed programs

advance development of the product to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding? Are development milestones clear and adequately described? Is the overall project timeline realistic? Are potential research and developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy? Does the applicant have the necessary experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and manufacturing? Does the team have access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan? If not, are there plans to address such deficiencies?

Financial Plan: Is there a comprehensive analysis of the aggregate funding required to market or exit and strategy to raise the required funding? If the applicant needs to raise further funds for the CPRIT matching requirement, how realistic are their assumptions about a successful fund-raising campaign? Do the development milestones and expected results of the research program reasonably support such assumptions? Has the applicant demonstrated that the returns are sufficient to justify the investment on a risk-adjusted basis?

Production/Manufacturing: How advanced is production /manufacturing development? Are there any sourcing issues? Has the applicant demonstrated that the product can be manufactured at commercial scale and with a reasonable cost? Are there significant technical difficulties still to be addressed?

9.3.2. Secondary Criteria

Secondary review criteria contribute to the global score assigned to the application and are not assigned individual numerical scores. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

Budget and Duration of Support: Are the budget and duration of support appropriate and realistic for the proposed project? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is there sufficient clarity in the budget proposal as to how funds will be

expended? Is there sufficient clarity in the budget proposal as to the spending of funds in Texas? Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

10. SUBMISSION GUIDELINES

Applicants are advised to review carefully all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available on May 29, 2018. Applications that are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

10.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The company applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the company applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. It is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires that the applicant and the ASO have 2 different accounts and user names. Applications will be accepted beginning at 7 AM central time on June 28, 2018, and must be submitted by 4 PM central time on August 8, 2018. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.2. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. Late submissions are permitted only in exceptional instances, usually for technology failures in the CARS. It is imperative that applicants allow sufficient time to familiarize themselves with the application

format and instructions to avoid unexpected issues. The applicant's failure to adequately plan is not sufficient grounds to justify approval of a late submission.

Peer review schedules are set far in advance and do not accommodate receipt of an application days after the deadline. Therefore, potential applicants that are unable to meet the deadline due to issues such as travel, sabbaticals, conferences, prolonged illness or other leave, etc, should not request additional time to submit an application but should instead consider submitting the application in the next review cycle.

A request to extend the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

10.3. Product Development Review Fee

All applicants must submit a nonrefundable fee of $500 for review of Product Development Research applications. Payment should be made by check or money order payable to Cancer Prevention and Research Institute of Texas; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit a late fee has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed to the following address:

Cancer Prevention and Research Institute of Texas
Travis State Office Building
1701 N Congress Ave Ste 6-127
Austin, Texas 78701

Contact name: Michelle Huddleston

Phone: 1-512-305-8420

10.4. Application Components

Applicants are advised to minimize repetition among application components to the extent possible. In addition, applicants should use discretion in cross-referencing sections to maximize the amount of information presented within the page limits.

Please note that letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc, are **not** required or requested. If applicants choose to include such

letters, they may only be added to the Development or Budget Plan sections and will count toward the page limit for that section.

10.4.1. Layperson's Summary (1,500-character maximum)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The layperson's summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

10.4.2. Slide Presentation (10-page maximum)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with 1 slide filling each landscape-orientated page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.4.3. Abstract and Significance (5,000-character maximum)

Coherently explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Address how the proposed project, if successful, will have a major impact on the care of patients with cancer. Describe how this application provides a path for acquiring proof-of-principle data necessary for next-stage commercial development. Clearly explain the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.4.4. Goals and Objectives (maximum of 1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. Identify time-specific references as follows: Year 1, Quarter 1 (Y1Q1), Y1Q2, etc. Do not specify actual calendar dates as this can be confusing when dates change.

10.4.5. Timeline (1-page maximum)

Provide a visual depiction of anticipated major milestones to be tracked in the form of a Gantt chart. Identify time-specific references as follows: Y1Q1, Y1Q2, etc, as opposed to naming specific months and years. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

10.4.6. Development Plan (12-page maximum)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. **Describe the label claims that the company ultimately hopes to make and describe the plan to gather evidence to support these claims**. Outline the steps to be taken during the proposed period of the award, including the design of the translational and/or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches to these risks. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The development plan should include a defined **target product profile (TPP)** or analogous document for a medical device, in vitro diagnostic, or service that projects a clear path to full commercialization (see http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm080593.pdf). The TPP provides a statement of the *overall intent* of the product development program and gives information about the product *at a particular time* in development. Usually,

the TPP is organized according to the key sections in the product package insert for a drug or biologic or medical device labeling and links development activities to specific concepts intended for inclusion in the product labeling. CPRIT recognizes that many applications are early in the development process and that not all elements of the TPP will be known at the time of application. Consequently, not only does the TPP serve as a snapshot in time of the development status of the program, but it additionally serves as an aspirational target upon eventual commercialization. The TPP should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, medical device, diagnostic, or service that could be useful in the treatment of cancer?
- Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
- Description of a high-level clinical development plan detailing each of the clinical studies supporting marketing approval (phase 1, 2, and 3) the preclinical work is meant to support. Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the phase 1, phase 2, and phase 3 studies necessary to obtain regulatory approval and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Applicants developing cancer therapeutics are encouraged to become familiar with FDA guidance documents for submission of applications related to new product development. These documents provide a standard framework for new drug submissions and biologic license applications to the FDA. Utilizing this framework helps ensure that the submission to CPRIT contains all relevant elements and is optimally organized.

Additionally, for therapeutics, the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or

will the use of this new agent require a paradigm shift (more frequent or less frequent dosing, new route or method of administration), and if so, what impact will it have on current standard of care?

Optimization of the lead to ensure desired characteristics, including, but not limited to, the following studies:

- Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced
- Absorption, distribution, metabolism, excretion, including, but not limited to, relevant studies based on route of administration
- Safety (studies as mandated by ICH guidelines)
- Biomarkers (assays) that potentially target specific patient populations for clinical trials
- Biomarkers (assays) that can serve as potential pharmacodynamic markers of clinical activity during early clinical trials designed to demonstrate proof of concept
- Proposed current good manufacturing practice (including estimated costs) that can be scalable from phase 1 through phase 2. Include information on whether there are plans for possible formulation.

The FDA's website provides "Common Technical Documents" (CTDs, see http://www.ich.org/products/ctd.html) guidance documents. There are 3 CTDs covering safety, efficacy, and quality. This guidance presents a standard format for the preparation of a well-structured application. Applicants may condense or summarize the CTD format as they deem appropriate to meet page limitations.

While originally intended for regulatory authorities, these formats are also applicable for a CPRIT application. Many of our reviewers have extensive pharmaceutical development expertise and are familiar with these standard formats. Hence, utilizing the CTD format will simplify the review and ensure that the application contains all of the relevant elements.

CPRIT recognizes that many applications are early in the product development process. Hence, not all elements of the CTD will be known at time of CPRIT application. We encourage applicants to complete as much of the Safety and Efficacy CTD sections as possible and to follow the submission format prescribed.

References for the Development Plan section should be provided as a stand-alone document that will be separately uploaded into CARS. In the interests of brevity include only the most pertinent and current literature. While references will not count toward the Development Plan section page limit, it is essential to be concise and to select only those references relevant to the development plan. **Do not use the references to circumvent Development Plan section page limits by including data analysis or other nonbibliographic material.**

The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. Please avoid redundancy!

CPRIT recognizes much, if not most, of this information is not available at this stage of development. However, we encourage applicants to be as complete as possible in describing their current stage of development. Applicants developing diagnostics, devices or cancer-specific services should provide analogous information relevant to their product and project.

10.4.7. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies typically need to raise substantial funds from private sources to fully fund development. Hence, we require companies to provide a business plan that summarizes the rationale for investing in this project. Private investors will seek a financial return on their investment. They will need to be convinced that this project has high investment return potential based on its risk profile. They typically focus on market opportunity size, development path, and key risk issues.

Successful applicants will provide thoughtful, careful, and succinct rationale explaining why this program is an appropriate investment of CPRIT and private funds. Note that if the company is selected to undergo due diligence, additional information to support the application will be requested at that time. Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

Please provide an overview of the business rationale for investing in this project. The business rationale overview will be 2 pages maximum. In addition, please provide summaries of the following 9 key development issues with a maximum of 1 page each.

1. **Product and Market:** Provide an overview of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc Information on patient populations and market segments is helpful.
2. **Competition and Value Proposition:** Provide an overview of the competitive environment (current and future) and how the envisioned product will compete in the marketplace. Provide information on how the clinical utility (efficacy, safety, cost, etc) of this therapy compares with current and potential future therapies. A clear delineation of competitive advantages and data demonstrating these advantages are helpful.
3. **Clinical and Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities and the regulatory pathway for major markets. Please describe how this is driven by interactions with the FDA, if possible. The regulatory plan should include regulatory communications (including all interactions to date with the FDA) and strategy, with clarity provided on regulatory matters and current regulatory strategies.
4. **Pricing and Reimbursement:** Provide an overview of the product cost and anticipated revenue. Cost, price, and reimbursement references from similar products are helpful. An overview of how the company plans to obtain CMS and private insurance reimbursement approval is also helpful.
5. **Commercial Strategy:** Provide an overview of your financial projections and how you will generate a return on this investment. Describe how the company plans to bring the product to market. Information on physicians to be targeted, sales channels, etc, is helpful. Alternatively, many drugs are acquired by large pharma firms in the late development stages. If the company plans to seek acquisition, please provide an overview of similar transactions.

6. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated. Key risk issues typically include efficacy versus competitors, toxicity, clinical trials, FDA approval, dosage and delivery, CMC synthesis, changing competitive environment, etc.

7. **Funding to Date:** Provide an overview of the funding received, including a list of funding sources and a comprehensive capitalization table that should comprise all parties who have investments, stock, or rights in the company. A template exemplifying an appropriate capitalization table is provided among the application materials. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.

8. **Intellectual Property:** Provide a concise discussion of the IP issues related to the project. List any relevant issued patents and patent applications. Please include the titles and dates the patents were issued/filed/published. List any licensing agreements that the company has signed that are relevant to this application.

9. **Key Personnel Located in Texas and Any Key Management Located Outside of Texas:** For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Key personnel are the Principal Investigator/Project Director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way. *Substantive* means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. *Measurable* means that they devote a specified percentage of time to the project. The indicated time is an obligatory commitment, regardless of whether or not they request salaries or compensation. “Zero percent” effort or “TBD” or “as needed” are not acceptable levels of involvement for those designated as key personnel. While all participants that meet these criteria should be identified as “key,” it is expected that the number of key personnel will be kept to a minimum.

The entire Business Plan section shall typically comprise a maximum of 11 pages: a 2-page overview and nine, 1-page key issue summaries. Please avoid redundancy. Note that the section "Funding to Date" above may exceed this 1-page limit if necessary.

CPRIT recognizes much, if not most, of this information is not available at this stage of development. However, we encourage applicants to be as complete as possible in describing their current stage of development. Applicants developing diagnostics, devices or cancer-specific services should provide analogous information relevant to their product and project.

10.4.8. Biographical Sketches of Key Scientific Personnel (8-page maximum)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. You may use the "Product Development Research Programs: Biographical Sketch" template but are not required to do so. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 10.4.7]).

10.4.9. Budget

In preparing the requested budget, applicants should be aware of the following:

- Each award mechanism allows for up to a 3-year funding program with an opportunity for extension after the term expires. **The budget must be aligned with the proposed milestones.** Financial support will be awarded based upon the breadth and nature of the project proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.
- CPRIT considers equipment to be items having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. If awarded, management of your grant will be facilitated if specific equipment is clearly identified in the application using plain language. **Equipment not listed in the applicant's budget must be specifically approved by CPRIT subsequent to the award contract**.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

- The total amount of CPRIT funds allowed for an annual salary of an individual for FY 2019 is $200,000. In other words, an individual may request salary proportional to the percentage effort up to a maximum of $200,000. Salary amounts in excess of this limit must be paid from matching funds. Salary does not include fringe benefits. CPRIT FY 2019 is from September 1, 2018, through August 31, 2019.

  Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of $200,000. The salary cap may be revised at CPRIT's discretion.

The Budget section is composed of 4 subtabs that must be completed:

A. **Budget for All Project Personnel:** Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project.

B. **Detailed Budget for Year 1:** This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Consultant Charges, Contractual (Subaward/Consortium), Research Related, or Other. Applicants will be required to itemize costs.

C. **Budget for Entire Proposed Period of Performance:** This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs for all subsequent years. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*.

D. **Budget Justification:** Please specify your CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds. Please specify each line item from your CPRIT budget as well as other funds (including matching funds). Provide a compelling justification for the budget for each line item of the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. **If travel costs will include out-of-state or international travel, make that clear here.** The budget must be aligned with the proposed milestones.

11. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and IP rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit periodic progress reports, typically quarterly. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

Project Revenue Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement, which can be found at www.cprit.texas.gov and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has appropriate matching funds. For companies receiving an initial CPRIT award, the company must contribute $1.00 in matching funds for every $2.00 awarded by CPRIT. CPRIT reserves the right to seek a higher matching funds contribution, ie, the company will contribute $1.00 in matching funds for every $1.00 awarded by CPRIT, from a company that has already received a CPRIT award and is approved for a second award. Matching funds need not be in hand when the application is submitted, nor does the entire amount of matching funds for the full 3 years of the project need to be available at the start of the grant. However, the appropriate amount of matching funds for each specific tranche must be obtained before each tranche of CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. **Before contacting the helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. In addition, for Frequently Asked Programmatic Questions, please go here and for Frequently Asked Technical Questions, please go here.**

Hours of operation: Monday through Friday, 8 AM to 6 PM central time

Tel: 866-941-7146 (toll free in United States only)

Email: Help@CPRITGrants.org

13.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Product Development Research Program Senior Manager.

Tel: 512-305-7676

Email: Help@CPRITGrants.org

Website: **www.cprit.texas.gov**

14. APPENDIX

14.1. Reviewer Evaluation Guidelines for Therapeutics

Primary Review Criteria (Scored)

Unmet medical need: Target Product Profile (TPP)

- Assuming successful accomplishment of development objectives, as reflected in the target product profile, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Target Validation

- If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
- Has engagement of the target with the agent been demonstrated by biochemical assay? What is the potency of the agent?
- Are there validated downstream pharmacodynamic (PD) markers of target modulation? How extensive is the in vitro evidence for expected PD effects? Has the agent shown biologically significant modulation of the target in vivo, especially in tumor tissue?
- Is the target uniquely or substantially overexpressed by tumor versus normal cells?
- Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
- Has the company's demonstration of target validation been externally/independently confirmed?
- Are there known mechanisms of resistance to the modulation of this target? If so, has the company proposed possible mitigation/preemptive approaches, such as combination chemotherapy?

Preclinical Characterization: Efficacy Proof of Concept

- Considering in vivo preclinical efficacy characterization and the patient populations or subpopulation(s) representing the initial clinical indication(s) for the drug, what is the

clinical relevance of the preclinical models? To elaborate, were in vivo/xenograft studies carried out in cell line–based models or PDX-derived models? In how many such models have studies been carried out? To what extent do these models reflect standard of care (SOC) for refractory versus drug-naive tumors? At the time of treatment initiation, were tumors established and measurable, or was treatment initiated shortly after tumor inoculation?

- Was antitumor activity predominantly growth inhibition or tumor regression? Were sustained complete remissions or "cures" achieved in the majority of animals and models? Were comparisons with optimally dosed SOC agents made? Where the agent is intended to be added to the SOC, is there compelling evidence of in vitro/in vivo synergy with SOC agents?
- Have results of preclinical efficacy studies carried out by the company been externally/independently confirmed?
- Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
- How strongly does the preclinical efficacy profile support the clinical efficacy expectations reflected in the TPP?

Preclinical Characterization: Safety

- How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
- Has the agent undergone CEREP-type screening for interactions with targets with known safety liabilities, eg, CYP 450, hERG?
- Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
- Can exposures associated with substantial antitumor efficacy/PD effects be achieved safely in vivo?
- Do preclinical pharmacokinetics (PK) studies indicate potential for clinical safety issues, eg, accumulation, variability, lack of dose proportionality?
- Have PK/PD issues been investigated with alternate dosing schedules to optimize the therapeutic index of the agent?
- Are there any issues with the distribution or metabolism of the agent?

- Overall, are results of safety characterization carried out so far such that the agent can be considered reasonably derisked from a safety perspective, or are there red flags? Alternatively, is the extent of preclinical safety characterization carried out so far insufficient to address this question?

Pharmaceutical Properties/Chemistry and Pharmacy

- In the case of agents intended for oral absorption, are there any issues with water solubility? Do formulation studies indicate the feasibility of oral administration?
- Were Lipinski-type criteria applied during the lead optimization process such that the lead compound has demonstrated properties that make it likely to be an orally active drug in humans?
- Are there any issues with the stability of the drug substance or the drug product?
- Is there scope for further lead optimization through structure-activity studies?
- In the case of biologicals, has a high-quality cell line been developed yet? Are yields acceptable? Does the purification process appear reasonable and scalable?
- Have analytical methods been adequately developed?
- Has the (lead) protein been adequately characterized biochemically, immunogenetically, and biophysically? Has absence of aggregate formation been demonstrated in stability studies?

Development Plan/Regulatory Aspects

- Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
- Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions (United States/European Union)? Do development proposals reflect specific regulatory authority input; eg, from pre-IND interactions? Alternatively, has regulatory authority interaction been insufficient so far?
- In the case of clinical studies, are patient populations adequately described and consistent with those representing the initial target indication(s)?
- Are efficacy end points appropriate for study designs? Is the sample size statistically adequately justified in terms of the target effect size?

- In the case of potentially pivotal clinical trials, moreover, are the proposed primary efficacy end points and target effect sizes consistent with regulatory precedence?
- Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
- Has the applicant demonstrated reasonable diligence in researching patient availability, competitive clinical trial activity, and recruitment issues such that patient enrollment projections can be considered realistic?
- Will the proposed programs advance development of the agent to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding?
- Are development milestones clear and adequately described? Is the overall project timeline realistic?

Competitive Analysis

- Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the agent compared to clinically relevant competitive products, including potentially competitive agents in development?
- Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable, considering the preclinical efficacy and safety data on the agent generated so far?

Intellectual Property/Freedom to Operate

- Have IP and freedom-to-operate aspects been addressed in the application?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate?

Chemistry, Manufacturing, and Controls (CMC)

- How advanced is CMC and manufacturing development?
- Are there any sourcing issues?

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- Are there significant technical difficulties within CMC/manufacturing scale up still to be addressed?

Business/Commercial Aspects

- Does the applicant need to raise further funds for the CPRIT matching requirement? In this case, how realistic are the applicant's assumptions about a successful fund-raising campaign? Does the applicant have a track record of success in raising development funding?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program of studies reasonably support such expectations?
- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and CMC/manufacturing? If not, are there plans to address such deficiencies?
- Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

14.2. Reviewer Evaluation Guidelines for Medical Devices and Diagnostics

Primary Review Criteria (Scored)

Product Validation

- Technical Validation: Has the product or technology been successfully validated, ie, prototyped, built and tested in ex vivo, animal, or clinical setting?
- Have biological proof of principle and product mechanism of action been demonstrated?
- Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
- Clinical Validation: Are clinical trials required to demonstrate product performance? If so, have they been planned or conducted?
- Biological Risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

Production/Manufacturing

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- How advanced is manufacturing development?
- Are there any sourcing issues?

Intellectual Property/Freedom to Operate

- Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique knowhow, etc?
- Does the company have issued patents? If not, have they conducted freedom to operate and patentability analysis?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use), and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has applicant secured appropriate licenses conferring freedom to operate, if required?

Market Opportunity

- Does product address a clearly defined unmet need; lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?

- Are target indication and market clearly defined?
- Is channel to market available? Does the company understand the entire value chain and all constituencies involved in procuring and utilizing the product?
- Does the company understand the clinical pathway that leads to utilizing the product?
- Is market opportunity of significant size and lucrative enough to justify investment?
- Has the applicant demonstrated time or cost savings?
- How does product fit with existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

Competition

- Is this a "Whole Product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
- Is value proposition clearly delineated, ie, improve efficacy, improve safety, reduce cost, or improve convenience?
- Has the company demonstrated its value proposition versus competition?
- Has the company conducted a competitive analysis? Does it provide a comprehensive, realistic assessment of strengths and weakness versus competition based on the data generated to date?

Development Plan

- Have a comprehensive development plan and market entry strategy been developed? How realistic are these plans?
- Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

Management and Staffing

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as product engineering, clinical development, regulatory affairs, manufacturing, etc? If not, are there plans to address such deficiencies?

- Has applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Financial Plan

- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration, and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?
- Has the company clearly anticipated pricing strategy and reimbursement environment?
- Is the projected return on investment congruent with investment opportunity and risks?

Funding

- Is investor interest in this sector sufficient to fund the company through profitability?
- Does the applicant already have available funds to meet the CPRIT matching requirement, or do they need to raise additional funds? In this case, how realistic are assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Have likely acquirers been identified by the applicant?
- Does the company have the resources to support required activities while fundraising?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program reasonably support such expectations?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Does the applicant demonstrate an understanding of the Texas spending requirement for CPRIT funds?

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
2019 Cycle 1 19.1 Product Development Panel-1 Meeting
(19.1-PDR_PDP-1)
Observation Report

Report No.	09-24-18_19.1-PDR_PDP-1
Program Name:	Product Development Research
Panel Name:	2019 Cycle 1 19.1 Product Development Panel-1 Meeting (19.1-PDR_PDP-1)
Panel Date:	9/24/2018
Report Date:	9/26/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 2019 Cycle 1 19.1 Product Development Panel-1 meeting. The meeting was chaired by Jack Geltosky and conducted via teleconference on September 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observer(s) noted the following during the meeting:

- Number (#) of applications: 15 applications were discussed and 5 applications were not discussed
- Panelists: One (1) panel chair and Ten (10) expert reviewers and Two (2) advocate reviewers
- ICON employees: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to clarifying policies, and answering procedural questions

There were two (2) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

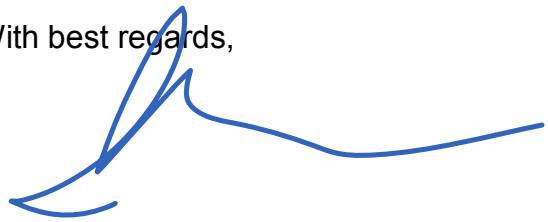
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
2019 Cycle 1 19.1 Product Development Panel-2 Meeting
(19.1-PDR_PDP-2)
Observation Report

Report No.	2018-09-25_19.1-PDR_PDP-2
Program Name:	Product Development Research
Panel Name:	2019 Cycle 1 19.1 Product Development Panel-2 Meeting (19.1-PDR_PDP-2)
Panel Date:	9/25/2018
Report Date:	9/27/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 2019 Cycle 1 19.1 Product Development Panel-2 meeting. The meeting was chaired by David Shoemaker and conducted via teleconference on September 25, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observer(s) noted the following during the meeting:

- Number (#) of applications: Eleven (11) applications were discussed and seven (7) were not discussed
- Panelists: One (1) panel chair and eleven (11) expert reviewers and two (2) advocate reviewers
- ICON employees: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

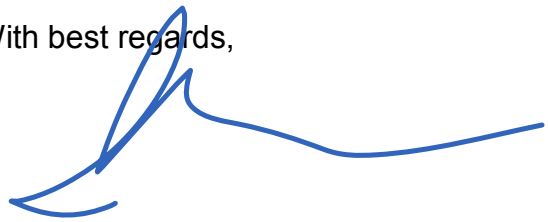
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Panel-1 Peer Review Meeting
(19.1_PDP-1)
Observation Report

Report No.	2018-10-23 19.1_PDP-1
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Panel-1 Peer Review Meeting (19.1_PDP-1)
Panel Date:	10-23/24-2018
Report Date:	10-30-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Panel-1 Peer Review (19.1_PDP-1) meeting. The meeting was chaired by Jack Geltosky and conducted via in-person in Dallas, Texas on October 23 and 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and Ten (10) were not discussed
- Panelists: One (1) panel chair and twelve (12) expert reviewers and two (2) advocate reviewers
- ICON employees: Two (2)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and four (4) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

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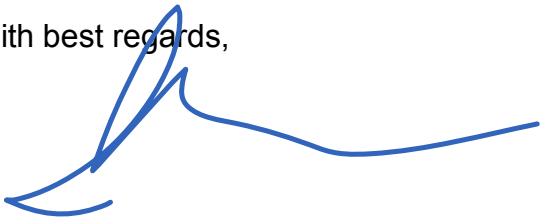
With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Panel-2 Peer Review Meeting
(19.1_PDP-2)
Observation Report

Report No.	2018-10-25 19.1_PDP-2
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Panel-2 Peer Review Meeting (19.1_PDP-2)
Panel Date:	10-25/26-2018
Report Date:	10-30-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Panel-2 Peer Review (19.1_PDP-2) meeting. The meeting was chaired by David Shoemaker and conducted via in-person in Dallas, Texas on October 25 and 26, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and eleven (11) were not discussed
- Panelists: One (1) panel chair and fourteen (14) expert reviewers and two (2) advocate reviewers
- ICON employees: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

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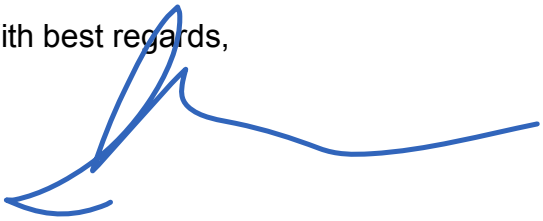
With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part - 1 Meeting
(19.1_PDR_DD_P-1)
Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-1
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 1 Meeting (19.1_PDR_DD_P-1)
Panel Date:	01-11-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 1 Meeting (19.1_PDR_DD_P-1). The meeting did not have an assigned chair; the duties were performed by David Shoemaker and conducted via teleconference on January 11, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: Ten (10) expert reviewers
- ICON employees: Six (6)
- IP Attorneys: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

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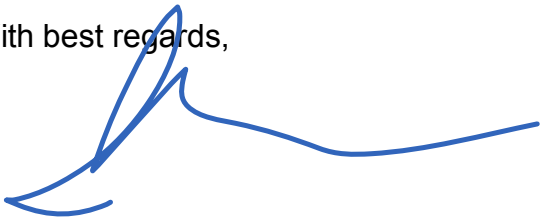
With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part - 2 Meeting
(19.1_PDR_DD_P-2)
Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-2
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 2 Meeting (19.1_PDR_DD_P-2)
Panel Date:	01-14-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 2 Meeting (19.1_PDR_DD_P-2). The meeting did not have an assigned chair; the duties were performed by Jack Geltosky and conducted via teleconference on January 14, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: Eight (8) expert reviewers
- ICON employees: Six (6)
- IP Attorneys: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

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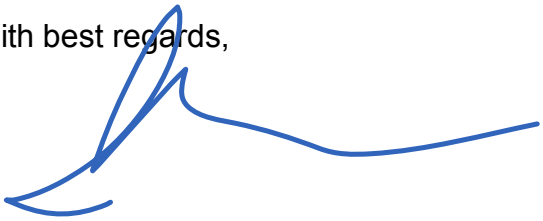

Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part – 2 Continuation Meeting (19.1_PDR_DD_P-2 con.) Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-2 Continuation
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 2 Continuation Meeting (19.1_PDR_DD_P-2 Con.)
Panel Date:	01-22-2019
Report Date:	01-23-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 2 Continutation Meeting (19.1_PDR_DD_P-2 Con.). The meeting did not have an assigned chair; the duties were performed by Jack Geltosky and conducted via teleconference on January 22, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: Six (6) expert reviewers
- ICON employees: Zero (0)
- IP Attorneys: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

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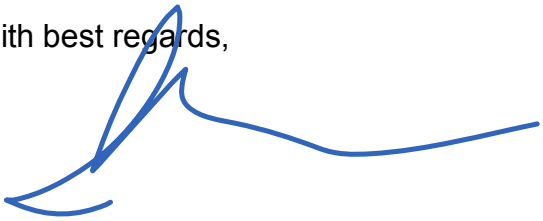

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Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Product Development Research Applications
(Product Development Research Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 19.1 include *Company Relocation Product Development Awards, Seed Awards for Product Development Research,* and *Texas Company Product Development Awards.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
DP190027	Piers Ingram	Hummingbird Bioscience Pte Ltd	V. Lee
DP190021	Kurt Gunter	Cell Medica	G. Williams;L. Greenberger
Applications not considered by the PIC or Oversight Committee			
DP190028	Laura Indolfi	PanTher Therapeutics, Inc	V. Lee
DP190035	Patrick Rivelli	Savran Technologies, Inc.	G. Cipau
DP190043*	Tania Fernandez	Midissia Therapeutics	H. Lyerly;V. Lee
DP190046	Mustapha Haddach	Pimera, Inc.	V. Lee
DP190047*	Sam Shrivastava	Venn Therapeutics, LLC	V. Lee
DP190060*	David Conway	Terra Biological LLC	V. Lee

High Level Summary of Due Diligence

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommends that the Program Integration Committee and the Oversight Committee approve the following Seed Awards for Product Development Research:

- Allterum Therapeutics, LLC for $2,912,313. The PDRC recommended contract contingencies for this award.
- Icell Kealex Therapeutics, LLC for $3,000,000. The PDRC recommended contract contingencies for this award.
- Instapath, Inc. for $3,000,000. No contract contingencies were recommended by the PDRC.

Allterum Therapeutics, LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Allterum Therapeutics, a Houston-based company, is developing a new drug for the treatment of pediatric T-cell acute lymphoblastic leukemia – a common form of childhood cancer. Although current treatments are effective for most children, approximately 20% of patients experience a recurrence of the disease. Allterum's drug is an antibody that is capable of more specifically targeting and killing cancer cells without the broad side effects typically observed with conventional therapies. Allterum addresses a major unmet medical need because the company expects the drug to be effective not only in children with recurring leukemia but to also to aid conventional chemotherapies when patients are first treated.

One reviewer summarized the significance and impact as follows: *This is a very strong application. It addresses an ultrarare population, pediatric patients with relapsed/refractory T-ALL, although it does have the potential of also being used in the first line due to a predicted better side effect profile than the drugs presently being used… The development plan is well thought out, and clearly the company is being run by people who have long experience doing this.*

Icell Kealex Therapeutics, LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Scientists from the Baylor College of Medicine founded Icell Kealex Therapeutics in 2015. The Houston-based company is developing an oncolytic virus designed to treat advanced solid tumors, including melanoma, breast cancer, colorectal cancer, pancreatic adenocarcinoma and ovarian cancer. The technology in development by Icell Kealex is engineered to overcome the

limitations of traditional virus-based therapies. The proposed project explores a novel concept for cancer virus therapy targeting multiple types of solid tumors.

One reviewer summarized the significance and impact as follows: *The applicant has a critically relevant concept for which they have some preclinical data and have already created the platform technology. The applicant has raised funds. The product would be hugely beneficial to an enormous variety of patients with solid tumors and is poised to be a multibillion dollar product. Compared to other SEED grantees, this applicant is farther along with research and development as well as funding. This application is potentially high reward to CPRIT for the modest investment.*

Instapath, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Seven million biopsy procedures are performed annually to diagnose cancer or collect tumor tissue for personalized therapy. Yet, due to inadequate biopsy tumor content, one in five biopsy procedures must be repeated to confirm diagnosis, and thousands of patients cannot receive potentially life-saving therapies because of downstream test failures. If doctors can quickly determine that a sample is insufficient, then they can collect more tissue immediately. However, currently available tests are too slow and destructive and require dedicated personnel.

Instapath, Inc. has developed an Automated Digital Pathology Lab (ADPL) imaging system that updates the traditional histology workflow, for the first time enabling users to go from the fresh sample directly to the histology image automatically and quickly. By making tissue adequacy testing fast, non-destructive, and fully automated, doctors can verify sample adequacy in less time with fewer personnel during the procedure, while there is still time to collect more tissue if needed. By producing images that can be reviewed remotely, the ADPL system may be transformative for the 92.52% of Texas counties that contain medically-underserved rural institutions without on-site pathologists. The ADPL system would allow for remote assessment and guidance of biopsy procedures, empowering hospital systems in underserved communities to provide higher quality of care with limited personnel resources.

One reviewer summarized the significance and impact as follows: *The applicant has a stellar concept—the creation of a fully automated pathology system. The human factor is reduced, which reduces error and leads to potentially highly effective (93%) results. The diagnosis of cancer accurately is critical. This product will reduce the need for repeat biopsies and save costs and time. Procedures could be done in half the time, and facilities could do 2x as many as presently. Moreover, due to the digital nature of the product, it will be hugely beneficial in the telemedicine arena.*

De-Identified Overall Evaluation Scores

Seed Awards for Product Development Research

Product Development Research Cycle 19.1

Application ID	Final Overall Evaluation Score
DP190018*	2.2
DP190025*	2.2
DP190020*	2.5
Va	2.7
Vb	3.9
Vc	4.0
Vd	4.0
Ve	4.1
Vf	4.3
Vg	4.4
Vh	4.5
Vi	4.5
Vj	4.5
Vk	4.5
Vl	4.6
Vm	4.8
Vn	5.4
Vo	5.5
Vp	5.8
Vq	6.0
Vr	6.0
Vs	6.0
Vt	6.0
Vy	6.5
vv	6.8

* Recommended for award

Final Overall Evaluation Scores and Rank Order Scores

January 23, 2019

Will Montgomery
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com
Via email to Will Montgomery's assistant, Laura Blevins, lblevins@jw.com

Wayne R. Roberts
Program Integration Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Will and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 19.1 grant award cycle.

The PDRC recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Hummingbird Bioscience, Allterum Therapeutics, Cell Medica, Icell Kealex Therapeutics and Instapath. The attached table reflects the ranked award recommendations, including the maximum recommended funding amounts and the overall evaluation scores for the five grant applications.

The PDRC did not make any changes to the goals, timelines, or budgets for the five projects recommended for funding. However, three of these recommendations are contingent on the review of the items described as follows:

- Execution of the CPRIT award contract for Allterum Therapeutics is contingent on the company's completion of the license agreement with the National Cancer Institute and CPRIT's review of documentation associated with the University of Maryland licensing agreement as outlined in the Vinson & Elkins IP Memorandum.
- Execution of the CPRIT award contract for Cell Medica is contingent on the company's completion of the recommendations set forth in the Vinson & Elkins IP Memorandum regarding patent coverage.
- Execution of the CPRIT award contract for Icell Kealex Therapeutics is contingent on resolution of the IP and licensing issues as outlined in the IP Diligence Memorandum from Baker Botts LLP.

The PDRC did not identify any contingencies associated with the awards to Hummingbird Bioscience or Instapath.

Each of companies included in the PDRC's recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PDRC's review of the due

diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

I will also note that the PDRC elected to take no action on two pending applications considered during due diligence review. Additional information is needed from the applicants before making final award decisions on DP190041 and DP190046. Once the applicants provide the requested information, the PDRC will reconvene and evaluate the data before making final award decisions. We anticipate that we will provide our award recommendations, if any, regarding these two pending proposals for consideration at either the May or August Oversight Committee meeting.

Sincerely,

/JG/ J Deltosky

Jack Geltosky, PhD

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations

FY 2019, Cycle 1

Rank	Application ID	Mech.	Company Name	Project	Maximum Recommended Budget	Overall Score
1	DP190027	RELCO	Hummingbird Bioscience Pte Ltd	A First-in-Class Anti-VISTA Monoclonal Antibody for the Treatment of MDSC-Mediated Suppression of Antitumor Immunity in Solid Tumors and Lymphomas	$13,116,095	2.0
2	DP190025	SEED	Allterum Therapeutics, LLC	Preclinical Development of a Novel T-ALL Therapeutic Antibody	$2,912,313	2.2
3	DP190020	SEED	Icell Kealex Therapeutics LLC	Development of a Novel Oncolytic Vaccinia Virus Variant Suitable for Systemic Delivery	$3,000,000	2.5
4	DP190021	TXCO	Cell Medica	Off-the-Shelf CAR-NKT Cells for Treatment of Solid and Hematological Malignancy	$8,742,509	3.1
5	DP190018	RELCO	Instapath Inc.	Rapid Pathology Evaluation System for Biopsies	$3,000,000	2.2
				Total	$30,770,917	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Tobacco Control and Lung Cancer Screening

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA P-19.1-TCL

Tobacco Control and Lung Cancer Screening

Please also refer to the Instructions for Applicants document, which will be posted on June 7, 2018

Application Receipt Opening Date: June 7, 2018

Application Receipt Closing Date September 5, 2018

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

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RFA VERSION HISTORY

Rev 05/10/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and enhance the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary, and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize underserved populations

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer.

The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies.

People who use tobacco products or who are regularly around environmental tobacco smoke have an increased risk of cancer because tobacco products and secondhand smoke contain many chemicals that damage DNA. Tobacco use causes many types of cancer, and there is no safe level of tobacco use. People who quit smoking, regardless of their age, have substantial gains in life expectancy compared with those who continue to smoke. Also, quitting smoking at the time of a cancer diagnosis reduces the risk of death.[1]

Tobacco use accounts for at least 30% of all cancer deaths, causing 83% of lung cancer deaths in men and 76% of lung cancer deaths in women.[2] Lung cancer is the leading cause of cancer-related mortality in Texas; in 2016 there were an estimated 9,438 deaths.[3]

The **Tobacco Control and Lung Cancer Screening (TCL)** award mechanism seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers.

This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth. In addition to evidence-based interventions for tobacco prevention and cessation, screening to detect cancer early, before it has spread, can reduce lung cancer mortality. For the early detection of lung cancer, the US Preventive Services Task Force (USPSTF) recommends annual lung cancer screening with low-dose computerized tomography (LDCT) for persons between the ages of 55 and 77 years old who have a history of heavy smoking (30 pack years or more) and who currently smoke or have quit within the past 15 years. The Centers for Medicare and Medicaid Services (CMS) has approved coverage and reimbursement for lung cancer screening for

individuals 55 to 77 years of age that meet their criteria. CMS also has eligibility criteria for radiologists and facilities delivering the screening services (https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274).

CPRIT will support programs screening individuals aged 55 to 77 that follow the CMS criteria for screening, radiologists, and facilities. CMS also requires delivery of smoking cessation counseling if LCDT screening is offered; however, for funding through this mechanism, CPRIT requires that robust evidence-based cessation interventions that go beyond offering only a referral or provision of information about smoking cessation interventions be delivered (see section 2.3 for details).

Programs proposed under this mechanism should be designed to reach and serve as many people as possible. Partnerships with other organizations that can support and leverage resources are strongly encouraged. A coordinated submission of a collaborative partnership program in which all partners have a substantial role in the proposed project is preferred.

2.2. Project Objectives

CPRIT seeks to fund projects that will address objectives listed under Option A **or** Option B:

A. Tobacco Prevention and Cessation for any age group

- Promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth including combustible cigarettes, oral tobacco products, and/or electronic devices that deliver nicotine.
- Increase the adoption and sustained implementation of evidence-based strategies by state and local public health agencies designed to reduce tobacco use.
- Increase the adoption and implementation of evidence-based strategies designed to mobilize communities, improve systems and programs to influence societal norms, and encourage and support individuals in adoption of tobacco prevention and cessation behaviors.
- Increase the adoption and sustained implementation of evidence-based strategies by clinicians designed to reduce tobacco use.
- Stimulate the creation, adoption, and implementation of evidence-based strategies and policies designed to significantly improve the effectiveness of health care or other systems in reducing tobacco use among the patients and employees of those systems.

- Implement policy changes and/or system improvements that are sustainable over time.
- Focus on underinsured and uninsured population groups by implementation of strategies and activities that may significantly reduce tobacco use and cancer-related disparities.

B. Lung Cancer Screening, Early Detection, and Cessation for individuals 55 to 77 years of age

- Develop, implement, and evaluate strategies to significantly increase use of LDCT screening for earlier detection of lung cancer following the USPSTF criteria and definition of high-risk populations (history of 30 pack years of smoking, individuals between 55 and 77 years of age who currently smoke or who have quit smoking within the past 15 years), as well as meet CMS eligibility criteria for radiologists and facilities
- Deliver evidence-based programming designed to significantly increase tobacco cessation among adults 55 to 77 years old that are being screened or considered for screening
- Deliver education for health care providers that includes, but is not limited to, earlier detection of lung cancer, diagnosis and treatment of lung cancer, shared decision-making about eligibility, risks and benefits of lung LDCT screening, tobacco cessation programming, and comprehensive behavioral health change initiatives
- Increase shared decision-making between the health care provider and patients about eligibility, risks, and benefits of lung LDCT screening
- Stimulate the creation, adoption, and implementation of evidence-based strategies and policies designed to significantly improve the effectiveness of health systems in reducing tobacco use among the patients being screened or considered for screening
- Implement policy changes and/or system improvements that are sustainable over time
- Focus on underinsured and uninsured population groups by implementation of strategies and activities that may significantly reduce tobacco use and cancer-related disparities

2.3. Award Description

The Tobacco Control and Lung Cancer Screening RFA solicits applications for projects that may be up to 36 months in duration that will deliver evidence-based interventions focused on tobacco

prevention (prevent tobacco use or sustained abstinence) and tobacco cessation among youth and/or adults. This RFA will also support LDCT screening for populations eligible for this intervention as defined by CMS if paired with evidence-based cessation interventions for the population to be screened.

As detailed below, projects may propose comprehensive tobacco cessation programs for youth and/or adults, **(Option A)**, **or** projects may propose programs that include comprehensive tobacco cessation programs plus LDCT lung cancer screening for eligible participants aged 55 to 77, **(Option B)**, **but not both**.

CPRIT's priorities include a focus on underserved populations and the targeting of areas and populations where significant disparities exist. Projects should propose to develop, adopt, and implement strategies and activities that have the potential to significantly reduce tobacco use and cancer-related disparities and serve underinsured and uninsured population groups. If addressing worksites, projects should focus on worksites that are likely to have limited or no health insurance; eg, part-time or hourly workers. (See priority populations, section 2.4).

Proposals are encouraged to incorporate evidence-based interventions such as those found in Community Guide to Reducing Tobacco Use and Secondhand Smoke Exposure; CDC Policies and Practices for Cancer Prevention: Lung Cancer Screening Programs; CDC Best Practices for Comprehensive Tobacco Control Programs; and American College of Chest Physicians/American Thoracic Society Policy statement on Components Necessary for High-Quality Lung Cancer Screening. In addition, USPSTF guidelines and CMS criteria must be met if providing LDCT screening.

The following are required components of the project:

Option A. Tobacco Prevention and Cessation services

Projects under this option for tobacco prevention and cessation services without LDCT screening must provide the following:

- Evidence-based tobacco prevention and tobacco cessation education and services for adults and/or youth that include behavioral as well as pharmacotherapy interventions (if such interventions are indicated for youth). Effective cessation interventions include individual, group, and telephone counseling as well as FDA-approved cessation medications.

Programs may include prevention and cessation of any product that delivers nicotine, including combustible cigarettes, oral tobacco products, and/or electronic devices.

In addition, projects should include SOME combination of the following:

- Evidence-based strategies delivered by public health officials (eg, state or local public health agencies) designed to reduce tobacco use and increase the adoption and sustained implementation of tobacco control programs;
- Evidence-based strategies designed to mobilize communities, improve systems and programs to influence societal norms, and encourage and support individuals in adoption of prevention and cessation behaviors (eg, NCI RTIPS interventions);
- Evidence-based strategies designed to improve the knowledge, skills, and effectiveness of health care providers in providing direct tobacco cessation interventions (eg, 5 A's approach); and
- Evidence-based strategies designed to improve the efficacy/effectiveness of health systems in tobacco cessation, including changes in how health systems approach tobacco cessation (eg, integration into EMRs, clinical workflows, well-visit protocols).

Option B. Lung Cancer screening and early detection services plus cessation services

Projects under this option that includes lung cancer LDCT screening and relevant diagnostic interventions in addition to robust evidence-based tobacco cessation interventions must include **ALL** of the following:

- LDCT lung cancer screening must be provided according to CMS and USPSTF guidelines.
- LDCT lung cancer screening facilities and radiologists must meet CMS requirements.
- Education for health care providers that includes, but is not limited to, earlier detection of lung cancer, diagnosis and treatment of lung cancer, tobacco cessation programming, and more comprehensive behavioral health change initiatives.
- Strategic educational initiatives for both the health care provider and patients focused on patient-centered health care that involves shared decision-making about eligibility, risks and benefits, and implementation of lung LDCT.
- The development, adoption, and implementation of robust evidence-based tobacco cessation interventions for individuals 55 to 77 years of age before screening as well as post LDCT screening. In cases where screening results are normal, cessation interventions

begun before the results of screening are received may increase the motivation to continue with cessation treatments.

- Cessation interventions must be comprehensive and robust and integrated with the screening program. Cessation interventions must involve more than handing out educational materials or referral to either the Quitline or other cessation resources and include behavioral as well as pharmacotherapy interventions. Cessation services offered outside the clinic setting require a formal agreement/memorandum of understanding for patient followup and confirmation of behavioral changes for the patients referred. Patient cessation outcomes are to be reported to CPRIT.
- The development, adoption, and implementation of enhancements and improvements in health and health care systems and/or policy that can increase the effectiveness of tobacco and cancer control (ie, integration into EMRs, clinical workflow, and well-visit protocols).
- The development, adoption, and implementation of procedures and protocols for frequent followup of patients to assess not only participation but successful outcomes regarding accessing cessation services, sustained abstinence, and outcomes known to be related to sustained cessation.
- The development, adoption, and implementation of system policies and protocols that include but are not limited to who should be offered screening within the USPSTF guidelines, frequency of screening, who should be followed, and who should proceed to surgical resection.
- Recognizing that there are false positives and false negatives in LDCT screening, the development, adoption, and implementation of evidence-based protocols for abnormal LDCT results.
- Patient navigation into treatment when cancer is diagnosed. Applicants must describe the resources available for treatment of uninsured/underinsured patients.

CPRIT's services grants are intended to fund prevention interventions that have a demonstrated evidence base and are culturally appropriate for the priority population.

CPRIT recognizes that evidence-based services have been developed but not implemented or tested in all populations or service settings. In such cases, other forms of evidence (eg, preliminary evaluation or pilot project data) that the proposed service is appropriate for the population and has a high likelihood of success must be provided. The applicant must fully describe the base of

evidence and any plans to adapt and evaluate the implementation of the program for the specific audience or situation.

CPRIT encourages traditional and nontraditional collaborative partnerships as well as leveraging of existing resources and dollars from other sources. A collaborative partnership is one in which all partners have a substantial role in the proposed project. Letters of commitment describing their role in the partnership are required from all partners.

CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based services, changes in provider practice, systems changes, and cost-effectiveness. Applicants must demonstrate how these outcomes will ultimately impact incidence, mortality, morbidity, or quality of life.

Under this RFA, CPRIT **will not** consider the following:

- **Projects focusing solely on case management/patient navigation services.** Case management/patient navigation services must be paired with tobacco prevention or cessation services. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.
- **Projects focusing on tobacco prevention and cessation education without the delivery of cessation or other clinical services.**
- **Projects requesting CPRIT funding for Quitline services.** Applicants proposing the utilization of Quitline services should communicate with the Tobacco Prevention and Control program prior to submitting a CPRIT grant application to discuss the services currently offered by the Texas Department of State Health Services (DSHS).
- **Projects involving prevention/intervention research.** Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).[4]

2.4. Priorities

Types of Cancer: Only projects proposing tobacco control interventions and lung cancer screening will be considered for funding. See section 2.5 for specific areas of emphasis.

The Prevention Program's priorities for funding include the following:

Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence: CPRIT programs must address underserved populations**.** Underserved populations are subgroups that are disproportionately affected by cancer. CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals;
- Medically unserved or underserved populations;
- Racial, ethnic, and cultural minority populations;
- Populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance with nationally recommended screening guidelines.

The age of the priority population and frequency of screening for provision of clinical services described in the application must comply with established and current national guidelines (eg, USPSTF, CMS, American Cancer Society).

Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence: While disparities and needs exist across the state, CPRIT will also prioritize applications proposing to serve geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence. In addition, projects addressing areas of emphasis (see section 2.5) will receive priority consideration.

Geographic and Population Balance in Current CPRIT portfolio: At the programmatic level of review conducted by the Prevention Review Council (see section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see http://www.cprit.texas.gov/prevention/resources-for-cancer-prevention-and-control and http://www.cprit.texas.gov/funded-grants).

2.5. Specific Areas of Emphasis

CPRIT has identified the following areas of emphasis for this cycle of awards.

Primary Prevention
Tobacco Prevention and Control
• Vulnerable and high-risk populations, including people with mental illness, history of substance abuse, youth, and pregnant women, that have higher tobacco usage rates than the general population.
• Areas that have higher smoking rates per capita than other areas of the state. Public Health Regions (PHR) 4, 5, and 9 have significantly higher tobacco use among adults than in other regions of the state.
Secondary Prevention - Screening and Early Detection Services
Lung Cancer
• Decreasing disparities in incidence and mortality rates of lung cancer in racial/ethnic populations. Blacks have higher mortality rates than Hispanics and non-Hispanic whites.
• Increasing screening/detection rates in PHR 2, 4, and 5, where the highest rates of cancer incidence and mortality are found.

2.6. Outcome Metrics

Applicants are required to clearly describe their assessment and evaluation methodology. The applicant is required to describe final outcome measures for the project. Output measures that are associated with the final outcome measures should be identified in the project plan and will serve as a measure of program effectiveness. Planned policy or system changes should be identified and the plan for qualitative analysis described. **Baseline data for each measure proposed are required**. In addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to establish a baseline. Applicants are required to fully describe any planned systems, policy changes, or improvements.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to, the following:
  - Summary page, including narrative on project progress (required);
  - Services, other than clinical services, provided to the public/professionals;
  - Actions taken by people/professionals as a result of education or training;
  - Clinical services provided (county of residence of client is required); and
  - Precursors and cancers detected.
- Annual and final progress report sections include, but are not limited to, the following:
  - Key accomplishments**, including qualitative analysis of policy change and/or lasting systems change** and;
  - Progress toward goals and outcome objectives, including percentage increase over baseline in provision of age- and risk-appropriate education and navigation services to eligible individuals in a defined service area;
  - Materials produced and publications;
  - Economic impact of the project.

2.7. Eligibility

- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field and who resides in Texas during the time that the project is conducted.

- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant may submit more than 1 application, but each application must be for distinctly different services without overlap in the services provided. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review.
- If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary.
- If the applicant or a partner is an existing DSHS contractor, CPRIT funds may not be used as a match, and the application must explain how this grant complements or leverages existing state and federal funds. DSHS contractors who also receive CPRIT funds must be in compliance with and fulfill all contractual obligations within CPRIT. CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor receiving funds from both entities.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non–Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.
- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud

or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 6. All statutory provisions and relevant administrative rules can be found at http://www.cprit.texas.gov.

2.8. Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

2.9. Continuation/Expansion Policy

- A grant recipient that has previously been awarded grant funding from CPRIT may submit an application under this mechanism to be considered for a continuation/expansion grant. The eligibility criteria described in section 2.7 also apply to continuation/expansion applications. Before submitting an application for this award, applicants should consult with the Prevention Program Office (see section 7.2) to determine whether it is appropriate for their organization to seek continuation/expansion funding at this time.
- Continuation/Expansion grants are intended to fund continuation or expansion of currently or previously funded projects that have demonstrated exemplary success, as evidenced by progress reports and project evaluations, and desire to further enhance their impact on priority populations. Detailed descriptions of **results, barriers, outcomes, and impact of the currently or previously funded project are required** (see outline of Most Recently Funded Project Summary, section 4.4.10.1).
- Proposed continuation/expansion projects should NOT be new projects but should closely follow the intent and core elements of the currently or previously funded project. Established infrastructure/processes and fully described prior project results are required. Improvements and expansion (eg, new geographic area, additional services, new populations) are strongly encouraged but will require justification. Expansion of current projects into geographic areas not well served by the CPRIT portfolio (see maps at http://www.cprit.texas.gov/prevention/cprit-portfolio-maps/), especially rural areas or subpopulations of urban areas that are not currently being served, will receive priority consideration. CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area). It is expected that baselines will have already been established and that continued improvement over baseline is demonstrated in the current application. However, in the case of a proposed expansion where no baseline data exist for the priority population, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline. Applicants must demonstrate how these outcomes will ultimately impact cancer incidence, mortality, morbidity, or quality of life.
- CPRIT also expects that applications for continuation **will not** require startup time, that applicants can demonstrate that they have overcome barriers encountered, and that

applicants have identified **lasting systems changes** that improve results, efficiency, and sustainability. Leveraging of resources and plans for dissemination are expected and should be well described.

2.10. Funding Information

Applicants may request any amount of funding up to a maximum of $1.5 million in total funding over a maximum of 36 months for new or continuation/expansion projects. Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference. Applicants offering screening services must ensure that there is access to treatment services for patients with cancers that are detected as a result of the program and must describe access to treatment services in their application.

While this mechanism will fund diagnostic workup of abnormal LDCT results, applicants are encouraged to find additional sources to support the costlier diagnostic tests that may be needed. Proposed programs should be designed to reach and serve as many people as possible, and costly diagnostic tests could limit the reach of the program. Review of the proposals includes budget considerations such as the average cost per service, whether the budget is appropriate and reasonable, and whether the proposal reflects a good investment of Texas public funds.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the **total** award amount.

2.11. Opportunity for Applied Research

Since lung cancer screening has only recently become an approved screening tool and may occur in a variety of settings, there remain many questions and opportunities for continued study to

optimize the pairing of smoking cessation services with lung cancer screening and to improve the outcomes of lung cancer screening. CPRIT encourages successful applicants to consider how they might leverage a Prevention grant award and the population being screened to address these or other research questions and apply to CPRIT's Academic Research Program.

Examples of potential research questions follow:

- What are the most effective components of outreach and education strategies designed to influence underserved populations to make good decisions about their health and participate in shared decision-making and lung cancer screening?
- What are the most formidable barriers influencing the initiation of tobacco cessation counseling and lung cancer screening among underserved population groups?
- What are the most effective components of evidence-based cessation interventions delivered in conjunction with LDCT screening?
- What are effective shared decision-making interventions for LDCT?
- What is the cost-effectiveness of LDCT alone and/or in conjunction with various evidence-based interventions for tobacco cessation?
- What are the most effective evidence-based protocols for diagnostic work up of lung nodules in community settings?
- Can risk models be developed to define subgroups that might disproportionately benefit or be harmed with LDCT screening?
- What is the role of biomarkers in LDCT screening?

3. KEY DATES

RFA

RFA release	May 10, 2018

Application

Online application opens	June 7, 2018, 7 AM central time
Application due	September 5, 2018, 4 PM central time
Application review	November 2018-Jauary 2019

Award

Award notification	February 2019
Anticipated start date	March 1, 2019

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1. *Instructions for Applicants* document

It is imperative that applicants read the accompanying instructions document for this RFA (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on June 7, 2018, and must be submitted by 4 PM central time on September 5, 2018. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted in CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details.

Submissions that are missing 1 or more components or do not meet the eligibility requirements may be administratively withdrawn without review.

4.4.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need in the specific service area. Include rates of incidence, mortality, and screening in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the priority population to be served.
- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) reached, unique people (public and/or professionals) served, and the number of services provided.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.4.2. Goals and Objectives (700 characters each)

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the metric within the stated objective. The maximum number is 3 goals with 3 objectives each. Projects will

be evaluated annually on progress toward **outcome** goals and objectives. See Appendix B for instructions on writing outcome goals and objectives.

A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. If a baseline has not been defined, applicants are required to explain plans to establish baseline and describe method(s) of measurement.

4.4.3. Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3, and Months 1, 2, 3, etc, as applicable instead of specific months or years (eg, Year 1, Months 3-5). Month 1 is the first full month of the grant award.

4.4.4. Project Plan (12 pages, fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below.

Background: Briefly present the rationale behind the proposed service, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the priority population. If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the target population and target service area are required where applicable.

Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are encouraged.

Goals and Objectives: Process objectives should be included in the project plan. Outcome goals and objectives will be entered in separate fields in CARS. However, if desired, outcome goals and objectives may be fully repeated or briefly summarized here. See Appendix B for instructions on writing goals and objectives.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Describe why this project is nonduplicative. If an organization has a current CPRIT grant that is the same or similar to the

prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary.

It is important to distinguish between Texas counties where the project proposes to deliver services and counties of residence of population served (see Appendix A for definitions and Instructions for Applicants). Only counties with service delivery should be listed in the Geographic Area to be Served section of the application. Projecting counties of residence of population served is not required but may be described in the project plan.

Clearly demonstrate the ability to provide the proposed service and describe how results will be improved over baseline and the ability to reach the priority population. If clinical services are being paid for and provided by others, the applicant must explain and report on the outcomes and services that are delivered to the people navigated by the program. Applicants must also clearly describe plans to **ensure access to treatment services** should cancer be detected.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the plan for outcome and output measurements, including qualitative analysis of policy and system changes. Describe data collection and management methods, data analyses, and anticipated results. Evaluation and reporting of results should be headed by a professional who has demonstrated expertise in the field. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

Program Sustainability: CPRIT funds projects that target needs not sufficiently covered by other funding sources. As CPRIT approaches the end of its funding authority in 2022, program sustainability is of paramount importance. CPRIT acknowledges that full maintenance and sustainability of CPRIT-funded projects may not be feasible, especially in cases involving the

delivery of clinical services. Educational and other less costly interventions may be more readily sustained. Full maintenance of a project, the ability of the grantee's setting or community to continue to deliver the health benefits of the intervention as funded, is not required; however, efforts toward sustainability are expected and must be described. Program sustainability capacity is defined as the ability to maintain a program and its benefits over time. Washington University in St Louis has developed a useful tool (Program Sustainability Assessment Tool) to assess program capacity for sustainability. They describe several factors that contribute to program sustainability. These factors include environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communication, and strategic planning. Applicants are not required to use this tool; however, it provides practical guidance on factors that should be considered and should be included in the application to describe a program's capacity for sustainability.

It is expected that steps toward building sustainability capacity for the program will be taken and plans for such be fully described in the application. For new programs, the applicant should describe the factors that will contribute to the program's sustainability and plans for sustainability beyond the project end date. For continuation projects, the applicant should assess and describe their current activities and capacity for sustainability and plans for sustainability beyond the project's end date.

Important factors to include in describing plans for sustainability include integration of the evidence-based intervention within the culture of the grantee's setting or community through policies and practices; plans for systems change that are sustainable over time (eg, improve provider practice, efficiency, cost-effectiveness); and activities (eg, training, identification of alternative resources, building internal assets) that build durable resources and enable the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention.

Dissemination and Replication: Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination efforts should consider the message, source, audience, and channel (Brownson, R.C., et al. *J Pub Health Manag Pract*. 24(2):102-111, March/April 2018). Dissemination methods may include, but are not limited to, presentations at workshops and seminars, one-on-one meetings, publications, news media, social media, etc.

While passive dissemination methods are common (eg, publications, presentations at professional meetings), plans should include some active dissemination methods (eg, meetings with stakeholders, blogs, social media.) Applicants should describe their dissemination plans. The plans should include the kinds of audiences to be targeted and methods for reaching the targeted audiences.

Replication by others is an additional way to disseminate the project. For applicable components, describe how the project or components of the project lend themselves to application by other communities and/or organizations in the state or expansion in the same communities. Describe what components of this project can be adapted to a larger or lower resource setting. Note that some programs may have unique resources and may not lend themselves to replication by others.

4.4.5. People Reached (Indirect Contact)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the types of indirect noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to Appendix A for definitions.

4.4.6. Number of Services Delivered (Direct Contact)

Provide the estimated overall number of services directly delivered to members of the public and to professionals by the funded project. Each service should be counted, regardless of the number of services one person receives. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimate provided. Refer to Appendix A for definitions.

4.4.7. Number of Unique People Served (Direct Contact)

Provide the estimated overall number of unique members of the public and professionals served by the funded project. One person may receive multiple services but should only be counted once here. Refer to Appendix A for definitions.

4.4.8. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed services.

4.4.9. Resubmission Summary

Use the template provided on the CARS (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed.

The summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.4.10. Continuation/Expansion Application Documents

If the project proposed is being submitted for competitive renewal, the additional document described in section 4.4.10.1 is required.

4.4.10.1 Most Recently Funded Project Summary (3 pages)

Upload a summary that outlines the progress made with the most recently funded CPRIT award. Applicants must describe results and outcomes of the most recently funded award and demonstrate why further funding is warranted.

Please note that a different set of reviewers from those assigned to the previously funded application may evaluate this application. Applicants should make it easy for reviewers to compare the most recently funded project with the proposed continuation/expansion project.

In the description, include the following:

- Describe the evidence-based intervention, its purpose, and how it was implemented in the priority population. Describe any adaptations made for the population served.
- List approved goals and objectives of the most recently funded grant.
- For each objective, provide the following:
    - Milestones/target dates and target metrics
    - Actual completion dates and metrics
- For the most recently funded project, describe major activities; significant results, including major findings, developments or conclusions (both positive and negative); and key outcomes. If the project has not yet ended, provide projections for completion dates and

final metrics. Include a discussion of objectives not fully met. Explain any barriers encountered and strategies used to overcome these.

- Describe steps taken toward sustainability for components of the projects. Fully describe systems or policy improvements and enhancements.
- Describe how project results were disseminated or plans for future dissemination of results.

4.4.11. CPRIT Grants Summary

Use the template provided on the CARS (https://CPRITGrants.org). Provide a listing of **all** CPRIT-funded projects of the PD or Co-PD, regardless of their connection to this application.

4.4.12. Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in section 2.10 will be administratively withdrawn.

- **Average Cost per Service:** The average cost per service will be automatically calculated from the total cost of the project divided by the total number of services delivered (refer to Appendix A). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Personnel:** The individual salary cap for CPRIT awards is $200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.

- **Services Costs:**
    - CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested.
    - CPRIT does not allow recovery of costs related to tests that have not been recommended by the USPSTF.
- **Other Expenses:**
    - **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is $25.
    - **Costs Not Related to Cancer Prevention and Control:** CPRIT does not allow recovery of any costs for services not related to cancer (eg, health physicals, HIV testing).
- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.13. Current and Pending Support and Sources of Funding

Use the template provided on the CARS (https://CPRITGrants.org). Describe the funding source and duration of **all** current and pending support for the proposed project, including a capitalization table that reflects private investors, if any.

4.4.14. Biographical Sketches

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

Use the Co-PD Biographical Sketch section ONLY if a Co-PD has been identified.

The evaluation professional must provide a biographical sketch in the Evaluation Professional Biographical Sketch section.

Up to 3 additional biographical sketches for key personnel may be provided in the Key Personnel Biographical Sketch section.

Each biographical sketch must not exceed 2 pages and should use the "Prevention Programs: Biographical Sketch" template provided on the CARS (https://CPRITGrants.org). Only biographical sketches will be accepted; do not submit resumes and/or CVs. If a position is not yet filled, please upload a job description.

4.4.15. Collaborating Organizations

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (eg, evaluation, clinical services, recruitment to screening).

4.4.16. Letters of Commitment (10 pages)

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program. Letters should be specific to the contribution of each organization.

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time

period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1. Primary Evaluation Criteria

Impact

- Do the proposed services address an important problem or need in cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Do the proposed project strategies reach a priority population (eg, low income, minority, rural) at high risk of cancer?
- For continuation/expansion projects, does the proposed project build on its initial results (baseline)? Does it go beyond the initial project to address what the applicant has learned or explore new partnerships, new audiences, or improvements to systems?
- Will the project reach and serve/impact an appropriate number of people based on the budget allocated to providing services and the cost of providing services?
- If applicable, have partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than the applicant organization's effort separately?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the priority population? Is the base of evidence clearly explained and referenced?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall program approach, strategy, and design clearly described and supported by established theory and practice? Are the proposed objectives and activities feasible within

the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?

- Has the applicant proposed policy changes and/or system improvements?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including followup for abnormal results and access to treatment?
- Does the program leverage partners and resources to maximize the reach of the services proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- Does the application provide a clear and appropriate plan for data collection and management and data analyses?
- Are clear baseline data provided for the priority population, or are clear plans included to collect baseline data?
- If an evidence-based intervention is being adapted in a population where it has not been implemented or tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services? Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?

- Have the appropriate personnel been recruited to implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?

Program Sustainability

- For new projects, does the applicant describe **some** factors that will help ensure their program's sustainability (eg, strong environmental support, partnerships, organizational capacity, etc) and their plans to build capacity for sustainability?
- For continuation/expansion projects, does the applicant describe their current activities and capacity for sustainability and plans for sustainability beyond the project's end date?
- Does the applicant describe steps that will be taken and components of the project that will be integrated into the organization through policies and practices?
- Does the applicant describe a plan for systems changes that are sustainable over time; eg, improve results, provider practice, efficiency, cost-effectiveness?
- Does the applicant describe steps that the applicant organization or other entities will take or components of the project that will remain (eg, trained personnel, identification of alternative resources, building internal assets) to continue the delivery of some or all components of the evidence-based intervention once CPRIT funding ends?

5.2.2. Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Replication

- Are plans for dissemination of the project's results and outcomes, including target audiences and methods, clearly described?
- Are active dissemination strategies included and described in the plan?
- Does the applicant describe whether and/or how the project lends itself to replication of all or some components of the project by others in the state?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports.

Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding the scope and focus of applications.

Before contacting the helpdesk, please refer to the *Instructions for Applicants* document (posted on June 7, 2018), which provides a step-by-step guide to using CARS.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

7.2. Program Questions

Questions regarding the CPRIT Prevention Program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8417

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov

8. RESOURCES

- The Texas Cancer Registry. http://www.dshs.state.tx.us/tcr or contact the Texas Cancer Registry at the Department of State Health Services.
- The Community Guide. http://www.thecommunityguide.org/index.html
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, R.C., Colditz G.A., and Proctor, E.K. (Editors). *Dissemination and Implementation Research in Health: Translating Science to Practice.* Oxford University Press, March 2012

- Program Sustainability Assessment Tool, copyright 2012, Washington University, St Louis, MO (https://cphss.wustl.edu/Projects/Pages/Sustainability-Framework-and-Assessment-Tool.aspx)
- Getting the Word Out: New Approaches for Disseminating Public Health Science; Brownson, R.C., et al, *Journal of Public Health Management & Practice*. 24(2):102-111, March/April 2018. https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out___New_Approaches_for.4.aspx
- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs. http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

9. REFERENCES

1. National Cancer Institute, https://www.cancer.gov
2. American Cancer Society, Cancer Facts and Figures 2016,

   http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016

3. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services. http://www.dshs.state.tx.us/tcr/default.shtm
4. Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

APPENDIX A: KEY TERMS

- **Activities:** A listing of the "who, what, when, where, and how" for each objective that will be accomplished
- **Capacity Building**: Any activity (eg, training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention
- **Clinical Services:** Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- **Counties of Residence of Population Served:** Counties where the project does not plan to have a physical presence but people who live in these counties have received services. This includes counties of residence of people or places of business of professionals who participate in or receive education, navigation, or clinical services. Examples include people traveling to receive services as a result of marketing and programs accessible via the website or social media. These counties may be described in the project plan and must be reported in the quarterly progress report.
- **Counties with Service Delivery:** Counties where an activity or service will occur and the project has a physical presence for the services provided. Examples include onsite outreach and educational activities and delivery of clinical services through clinics, mobile vans, or telemedicine consults. These counties must be entered in the Geographic Area to be Served section of the application.
- **Education Services:** Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to health care professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments.
- **Evidence-Based Program:** A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-

based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit http://www.cprit.texas.gov/prevention/resources-for-cancer-prevention-and-control.

- **Goals:** Broad statements of general purpose to guide planning. Outcome goals should be few in number and focus on aspects of highest importance to the project. (Appendix B)
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- **Navigation Services:** Number of unique activities/services that offer assistance to help overcome health care system barriers in a timely and informative manner and facilitate cancer screening and diagnosis to improve health care access and outcomes. Examples include patient reminders, transportation assistance, and appointment scheduling assistance.
- **Number of Services (Direct Contact):** Number of services delivered directly to members of the public and/or professionals—direct, interactive public or professional education, outreach, training, navigation service, or clinical service, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. Note that one individual may receive multiple services.
- **Objectives:** Specific, **measurable,** actionable, realistic, and timely projections for outcomes; example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the priority population must be included as part of each objective. (Appendix B)
- **People Reached (Indirect contact):** Number of members of the public and/or professionals reached via indirect noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. (This category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.)
- **People Served (Direct Contact):** Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation

service, or clinical service. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.

APPENDIX B: WRITING GOALS AND OBJECTIVES

Adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604

Develop well-defined outcome goals and objectives.

Goals provide a roadmap or plan for where a group wants to go. Goals can be long term (over several years) or short term (over several months). Goals should be based on needs of the community and evidence-based data.

Goals should be:

- Believable – situations or conditions that the group believes can be achieved
- Attainable – possible within a designated time
- Tangible – capable of being understood or realized
- On a timetable – with a completion date
- Win-Win – beneficial to individual members and the coalition

Objectives are measurable steps toward achieving the goal. They are clear statements of specific activities required to achieve the goal. The best objectives have several characteristics in common – S.M.A.R.T. + C:

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)
    - Example: 115 uninsured individuals age 50 and older will complete colorectal cancer screening by March 31, 2019.
- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective
    - Example: How many screened at an event? How many completed pre/post assessment?
- Achievable – not only are the objectives themselves possible, it is likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved

- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

Review your developed objectives and determine the type and level of each using the following information:

There are 2 types of objectives:

- Outcome objectives – measure the "what" of a program; should be in the Goals and Objectives form (see section 4.4.2)
- Process objectives – measure the "how" of a program; should be in the project plan only (see section 4.4.4)

There are 3 levels of objectives:

- Community-level – objectives measure the planned community change
- Program impact – objectives measure the impact the program will have on a specific group of people
- Individual – objectives measures participant changes resulting from a specific program, using these factors:
    - Knowledge – understanding (know screening guidelines; recall the number to call for screening)
    - Attitudes – feeling about something (will consider secondhand smoke dangerous; believe eating 5 or more fruits and vegetable is important)
    - Skills – the ability to do something (complete fecal occult blood test)
    - Intentions – regarding plan for future behavior (will agree to talk to the doctor, will plan to schedule a Pap test)
    - Behaviors (past or current) – to act in a particular way (will exercise 30+ minutes a day, will have a mammogram)

Well-defined outcome goals and objectives can be used to track, measure, and report progress toward achievement.

	Outcome – Use in Goals and Objectives	Process – Use in Project Plan only
Community-level	WHAT will change in a community ***Example:*** *As a result of CPRIT funding, FIT (fecal immunochemical tests) will be available to 1,500 uninsured individuals age 50 and over through 10 participating local clinics and doctors.*	HOW the community change will come about ***Example:*** *Contracts will be signed with participating local providers to enable uninsured individuals over age 50 have access to free colorectal cancer screening in their communities.*
Program impact	WHAT will change in the target group as a result of a particular program ***Example:*** *As a result of this project, 200 uninsured women between 40 and 49 will receive free breast and cervical cancer screening.*	HOW the program will be implemented to affect change in a group/population ***Example:*** *2,000 female clients, between 40 and 49, will receive a letter inviting them to participate in breast and cervical cancer screening.*
Individual	WHAT an individual will learn as a result of a particular program, or WHAT change an individual will make as a result of a particular program ***Example:*** *As a result of one-to-one education of 500 individuals, at least 20% of participants will participate in a smoking cessation program to quit smoking.*	HOW the program will be implemented to affect change in an individual's knowledge or actions ***Example:*** *As a result of one-to-one counseling, all participants will identify at least 1 smoking cessation service and 1 smoking cessation aid.*

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Prevention Peer Review Meeting Panel 1
(19.1_PRV_ Panel PP-1)
Observation Report

Report No.	2018 – 12 – 12 19.1_PRV_ Panel PP-1
Program Name:	Prevention
Panel Name:	Prevention Peer Review Meeting Panel 1 (19.1_PRV_ Panel PP-1)
Panel Date:	12-11-2018 and 12-12-18
Report Date:	12-14-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Prevention Peer Review Meeting Panel 1 (19.1_PRV_ Panel PP-1) meeting. The meeting was chaired by Ross Brownson and Nancy Lee and conducted via in-person on December 11, 2018 and December 12, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Sixteen (16) applications were discussed and four (4) were not discussed
- Panelists: Two (2) panel chairs and eleven (11) expert reviewers and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Six (6)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

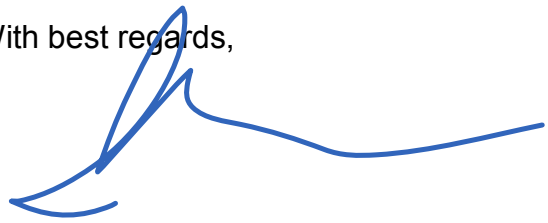
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Prevention Review Council Programmatic Review Meeting
(19.1_PRV_PRC)
Observation Report

Report No.	2019-01-11 19.1_PRV_PRC
Program Name:	Prevention
Panel Name:	Prevention Review Council Programmatic Review Meeting (19.1_PRV_PRC)
Panel Date:	01-11-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Prevention Review Council Programmatic Review Meeting (19.1_PRV_PRC). The meeting was chaired by Stephen Wyatt and conducted via teleconference on January 11, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and one (1) Dissemination mechanism project was added into the funding and rank order discussion
- Panelists: One (1) panel chair and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) COIs identified prior to and/or during the meeting. One reviewer with two declared (2) COIs was not a member of the review council and thus not present for this meeting. One reviewer with two (2) COIs was excluded from discussions concerning one application for which there was a conflict, but not the other.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

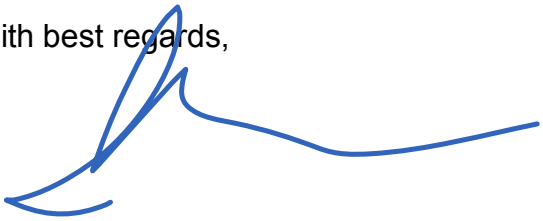
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Prevention 19.1 Applications
(Prevention Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 19.1 include *Evidence Based Cancer Prevention Services, Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations,* and *Tobacco Control and Lung Cancer Screening.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
PP190014	Kathleen Schmeler	The University of Texas M. D. Anderson Cancer Center	H. Brandt; R. Brownson
Applications not considered by the PIC or Oversight Committee			
PP190029	Lara Savas	The University of Texas Health Science Center at Houston	H. Brandt; R. Brownson

De-Identified Overall Evaluation Scores

Tobacco Control & Lung Cancer Screening

Prevention Cycle 19.1

Application ID	Final Overall Evaluation Score
PP190009*	2.1
PP190027*	2.7
ta	4.8
tb	6.5

* Recommended for award

Final Overall Evaluation Scores and Rank Order Scores

Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com
Via email to Will Montgomery assistant, Laura Blevins, lblevins@jw.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Roberts and Mr. Montgomery,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2019.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants.

The funding available for the fiscal year 2019 is $28,022,956. These recommended projects total $12,328,462.

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC continued to consider the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

Prevention Review Council Recommendations January 11, 2019											
Application ID	**Mechanism**	**Type**	**Application Title**	**PD**	**Organization**	**Total Requested Budget**	**Average Overall Score**	**Standard Deviation**	**Rank Order**	**Comments**	**Rec Budget**
PP190009	TCL	Resubmission	Expanding Tobacco Use Cessation in Northeast Texas	Prokhorov, Alexander V	The University of Texas M. D. Anderson Cancer Center	$1,499,956	2.1	0.6	1	Potential for Impact/Return on Investment and Type of	$1,499,956
PP190027	TCL	New	Engaging Oral Health Providers for Evidence-Based Tobacco Cessation	Jones, Daniel L	Texas A&M University System Health Science Center	$1,499,871	2.7	1.0	2	Potential for Impact/Return on Investment and Type of Program-Tobacco Control	$1,499,871
PP190004	EPS	Resubmission	Partnering with schools and clinics to expand a highly successful HPV vaccination program for 9-17 year olds from Medically Underserved Areas	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$2,499,411	1.5	0.5	3		$2,499,411
PP190021	EPS	New	Access to Breast and Cervical Care for west Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	$2,430,998	1.6	0.5	4		$2,430,998
PP190023	EPS	New	School-based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuation and Expansion to Hidalgo County	Rodriguez, Ana M	The University of Texas Medical Branch at Galveston	$1,969,731	1.9	0.3	5		$1,969,731
PP190014	EPS	New	Expansion of cervical cancer prevention services to medically underserved populations through patient outreach, navigation & provider training/telementoring	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	$2,128,529	2.6	0.8	6	Type of Program (EPS versus DI) and Potential for Impact/Return on Investment	$2,128,529
PP190041	DI	Resubmission	Adolescent Vaccination Program: Online Decision Support for Adoption of Evidence-based HPV Vaccination Strategies by Texas Pediatric Clinics	Shegog, Ross	The University of Texas Health Science Center at Houston	$299,966	2.0	0.0	7		$299,966

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycle 1
Texas Company Product Development Awards

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA C-19.1-TXCO

Texas Company Product Development Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on May 29, 2018

Application Receipt Opening Date: June 28, 2018

Application Receipt Closing Date: August 8, 2018

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 05/17/2018 RFA release

Rev 05/29/2018 RFA was revised (section 8.1, p. 10) informing applicants to submit only one Product Development Research application per cycle.

1. KEY POINTS

This Texas Company Product Development Research Award mechanism is governed by the following restrictions:

- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools.
- For therapeutics, Product Development Research award funding supports preclinical research and early clinical research necessary to demonstrate initial clinical safety and efficacy (typically phase 1, phase 2A).
- Recipient companies must currently be or commit to be Texas based (see section 8.1). The Cancer Prevention and Research Institute of Texas (CPRIT) requires the use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities.
- CPRIT requires recipient companies to raise a portion of the total project budget from external sources. For a company receiving an initial CPRIT award, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the recipient company. CPRIT reserves the right to seek a higher matching funds contribution (ie, CPRIT will contribute $1.00 for every $1.00 contributed in matching funds by the company) from a company that has already received a CPRIT award and is approved for a second award. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds should, whenever possible, be spent in Texas. A company's matching funds must be dedicated to the CPRIT-funded project but may be spent outside of Texas.
- Applicants may request up to $20 million in CPRIT funds. CPRIT receives many more applications each year than available funds can support. While all requests for funding must be well justified, a funding request at or near the maximum amount will be heavily scrutinized. Such a request must be exceptionally well justified to warrant dedicating a large percentage of CPRIT's product development research budget to the applicant's project.
- Funding will be tranched and tied to the achievement of contract-specified milestones.
- All award contracts include a revenue-sharing agreement. **A copy of the revenue-sharing agreement can be found at www.cprit.texas.gov in the Product Development**

Research Program section. Other contract provisions are specified in CPRIT's Administrative Rules, which are also available at www.cprit.texas.gov.

- An application last submitted but not funded (including resubmission) before June 28, 2016, may be submitted as a new application, even if it was previously resubmitted (see section 8.2).

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Research Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Product Development Research Program's principles and priorities will also guide CPRIT staff and the Product Development Review Council on the development and issuance of

program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of patients with cancer
- Creation of good, high-paying jobs for Texans
- Sound financial return on the monies invested
- Development of the Texas high-tech life sciences business environment

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available; ie, disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early-stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff, to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

A full description of CPRIT's program priorities may be found at http://www.cprit.texas.gov/about-cprit/reports/.

3. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This RFA solicits applications for the research and development of innovative products addressing critically important needs related to diagnosis, prevention, and/or treatment of cancer and the product development infrastructure needed to support these efforts. CPRIT encourages applicants who seek to apply or develop state-of-the-art products, services (eg, contract research organization

services), technologies, tools, and/or resources for cancer research, prevention, or treatment. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by increasing the availability of Food and Drug Administration (FDA)–approved therapeutic interventions with a primary focus on Texas-centric programs.

4. MECHANISM OF SUPPORT

The goal of the Texas Company Product Development Research Award is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will provide companies or limited partnerships located and headquartered in Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

5. OBJECTIVES

The long-term objective of this award is to support commercially oriented therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA should be the intent to further the research and development of products that would eventually be approved and marketed for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques.

CPRIT seeks to maximize the clinical impact of our funding. Hence, we focus investment in translational research and development activities, including the following eligible stages:

- Studies that establish preclinical proof of concept;
- GLP studies to support INDs;

- Phase 1 to establish safety and a maximally tolerated dose;
- Phase 2 studies to determine safety and efficacy in initial targeted patient populations (up to 100 patients).

CPRIT typically does not fund efforts outside of these parameters. We do not consider studies larger than what are described as "translational" and, hence, such studies are outside the scope of our interest. Companies that have clinically demonstrated safety and efficacy should be able to acquire necessary capital via other sources. By exception, later clinical trials or later-stage product development projects may be considered where exceptional circumstances warrant CPRIT investment.

CPRIT's objectives and program priorities are established by its Oversight Committee. Consistent with the above, these priorities include, "funding projects at Texas companies and relocating companies that are most likely to bring important products to the market." A full description of CPRIT's program priorities may be found at http://www.cprit.texas.gov/about-cprit/reports/.

6. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development project proposed. Requested funds must be well justified. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property (IP) protection, external consultants and service providers, travel in support of the project, and other appropriate research and development costs, subject to certain limitations set forth by Texas law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state. Texas law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

For companies receiving an initial CPRIT award, CPRIT will award $2.00 for every $1.00 contributed in matching funds by the company. CPRIT reserves the right to seek a higher matching funds contribution, ie, CPRIT will contribute $1.00 for every $1.00 contributed in

matching funds by the company) from a company that has already received a CPRIT award and is approved for a second award. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be fulfilled on a year-by-year basis.

7. KEY DATES

RFA release	May 17, 2018
Online application opens	June 28, 2018, 7 AM central time
Applications due	August 8, 2018, 4 PM central time
Invitations to present sent	October 2018
Notifications sent if not invited	October 2018
Presentations to CPRIT*	October 2018
Award Notification	February 2019
Anticipated Start Date	March 2019

* Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

8. ELIGIBILITY

8.1. Applicants

- Recipient companies must be Texas based. A company is considered to be Texas based if it currently fulfills or commits to fulfilling a majority of the following criteria:

    1. The US headquarters are physically located in Texas.
    2. The Chief Executive Officer resides in Texas.
    3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.
    4. Manufacturing activities take place in Texas.
    5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.

6. At least 1 clinical trial site is in Texas.

7. The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

Companies are typically required to meet the first 3 criteria. CPRIT recognizes meeting each of criteria 4 through 7 may not always be feasible. Hence, CPRIT may afford flexibility with these requirements, in specific circumstances, provided a majority of criteria are met. In exceptional circumstances, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

Unless otherwise specified by the award contract, all location requirements identified by the applicant must be fulfilled within 1 year of receiving the initial disbursement of funds. Failure to maintain compliance with the location criteria will result in consequences ranging from suspension of grant funding to early termination of the grant contract and repayment of grant funds.

- An applicant may submit only 1 application under this RFA during this funding cycle.
- An application last submitted (including resubmissions) before June 28, 2016 may be submitted as a new application, even if it was previously resubmitted.
- Please note that in any given application round, applicants will typically only be allowed to apply for <u>one</u> Product Development award (TXCO, RELCO or Seed) at a time. Applicants are advised to review each RFA and select the program that best fits their development status.
- Only 1 coapplicant may be included on the application. For the Product Development Research Program, a coapplicant is an individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, coapplicants share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple applicants are named, each is responsible and accountable for the proper conduct of the project, program, or activity, including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.

- A company applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individual within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- A company applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The company applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or other individuals are ineligible to receive federal grant funds or have had a grant terminated for cause, the applicant may be contacted to provide more information.
- CPRIT grants will be awarded by contract to successful company applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the company applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

8.2. Resubmission Policy

- An application previously submitted to CPRIT within the last 2 years (after June 28, 2016) but not funded may be resubmitted once and must follow all resubmission guidelines (see section 10.4.6). **An application that was last submitted (including a resubmission to CPRIT) before June 28, 2016, may be submitted as a new application, even if the most recent submittal prior to June 28, 2016, was a**

resubmission. It is expected that significant progress will have been made on the project; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to submit an application with such modest changes.

- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. An application that was administratively withdrawn by the applicant or by CPRIT prior to review by the review panel is not considered a submission for purposes of CPRIT's resubmission policy.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received an overall numerical score of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9. APPLICATION REVIEW

9.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT requires the submission of a comprehensive development plan (see section 10.4.7) and a detailed business plan (see section 10.4.8). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and development plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational

and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made via the review process described below.

9.2. Review Process

- **Product Development and Scientific Review:** Applications that pass initial administrative review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of company applicants may be invited to deliver in-person presentations to the review panel.
- **Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—IP, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications may be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and IP reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.
- **Program Integration Committee Review:** Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.
- **Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Any form of communication regarding any aspect of a pending application is prohibited between the company applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The**

overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

Attached to this RFA is a list of more detailed questions considered by CPRIT reviewers when assessing therapeutic applications (Appendix 1, at the end of this document, titled "Reviewer Evaluation Guidelines for Therapeutics") and when assessing medical devices, diagnostics and/or tools (Appendix 2, "Reviewer Evaluations Guidelines for Medical Devices and Diagnostics"). Applicants are encouraged to review these documents and, to the extent possible, address the questions within their application.

9.3.1. Primary Criteria

Primary review criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study.

The criteria provided below are designed to provide an **overview** of topics that may be pertinent to the assessment of applications during peer review. Specific criteria applied to evaluate a given application will depend on the type of product described by the applicant (eg, therapeutic versus medical device). **Detailed descriptions of the specific criteria employed for different product classes are provided in the appendices to this RFA.**

Primary review criteria are heavily weighted in determining the quality of an application. Reviewers provide numerical scores for these topic areas when evaluating applications. Primary criteria are intended to address the following topics:

Significance and Impact: Will the outcomes of this CPRIT-funded project result in the development of innovative products with significant product development potential? Will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?

Market Plan: Is there a realistic assessment of the market size and expected penetration? Has the applicant addressed patients, market segments, value proposition, pricing, outcomes research, sales plans, marketing research plans, or results? If the applicant plans to seek acquisition by a strategic partner, is there a well-characterized analysis of exit strategy and valuation? Is there an appropriate basis for a reimbursement strategy? Considering the initial clinical indications for the

product, its competitive strengths/weaknesses and pricing/reimbursement objectives, are market/segment penetration and sales/profitability projections reasonable?

Clinical/Regulatory Plan: Is the clinical and regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both positive and negative outcomes? Does the budget appropriately support the plan? Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions, eg, United States/European Union? Do development proposals reflect specific regulatory authority input?

Competitive Landscape: Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the product compared to clinically relevant, competitive products, including potentially competitive agents in development? Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable?

Intellectual Property: Considering patent type (Composition of Matter/ Formulation/ Manufacturing Process/Use) and duration of patent life, how strong is the IP?

Are there opportunities for meaningful patent life extension? Has the applicant secured appropriate licenses conferring freedom to operate?

Development Plan: Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date? Will the proposed programs advance development of the product to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding? Are development milestones clear and adequately described? Is the overall project timeline realistic? Are potential research and developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy? Does the applicant have the necessary experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and manufacturing? Does the team have access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan? If not, are there plans to address such deficiencies?

Financial Plan: Is there a comprehensive analysis of the aggregate funding required to market or exit and strategy to raise the required funding? If the applicant needs to raise further funds for the CPRIT matching requirement, how realistic are their assumptions about a successful fund-raising campaign? Do the development milestones and expected results of the research program reasonably support such assumptions? Has the applicant demonstrated that the returns are sufficient to justify the investment on a risk-adjusted basis?

Production/Manufacturing: How advanced is production/manufacturing development? Are there any sourcing issues? Has the applicant demonstrated that the product can be manufactured at commercial scale and with a reasonable cost? Are there significant technical difficulties still to be addressed?

9.3.2. Secondary Criteria

Secondary review criteria contribute to the global score assigned to the application and are not assigned individual numerical scores. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

Budget and Duration of Support: Are the budget and duration of support appropriate and realistic for the proposed project? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is there sufficient clarity in the budget proposal as to how funds will be expended? Is there sufficient clarity in the budget proposal as to the spending of funds in Texas? Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

10. SUBMISSION GUIDELINES

Applicants are advised to review carefully all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available on May 29, 2018. Applications that are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

10.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The company applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the company applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. It is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires that the applicant and the ASO have 2 different accounts and user names. Applications will be accepted beginning at 7 AM central time on June 28, 2018 and must be submitted by 4 PM central time on August 8, 2018. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.2. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. Late submissions are permitted only in exceptional instances, usually for technology failures in the CARS. It is imperative that applicants allow sufficient time to familiarize themselves with the application format and instructions to avoid unexpected issues. The applicant's failure to adequately plan is not sufficient grounds to justify approval of a late submission.

Peer review schedules are set far in advance and do not accommodate receipt of an application days after the deadline. Therefore, potential applicants that are unable to meet the deadline due to issues such as travel, sabbaticals, conferences, prolonged illness, or other leave, etc, should not request additional time to submit an application but should instead consider submitting the application in the next review cycle.

A request to extend the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

10.3. Product Development Review Fee

All applicants must submit a nonrefundable fee of $1,000 for review of Product Development Research applications. Payment should be made by check or money order payable to Cancer Prevention and Research Institute of Texas; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit a late fee has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed to the following address:

Cancer Prevention and Research Institute of Texas
Travis State Office Building
1701 N Congress Ave Ste 6-127
Austin, Texas 78701

Contact name: Michelle Huddleston

Phone 1-512-305-8420

10.4. Application Components

Applicants are advised to minimize repetition among application components to the extent possible. In addition, applicants should use discretion in cross-referencing sections to maximize the amount of information presented within the page limits.

Please note that letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc, are **not** required or requested. If applicants choose to include such letters, they may only be added to the Development or Budget Plan sections and will count toward the page limit for that section.

10.4.1. Layperson's Summary (1,500-character maximum)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with

cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The layperson's summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

10.4.2. Slide Presentation (10-page maximum)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with 1 slide filling each landscape-orientated page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.4.3. Abstract and Significance (5,000-character maximum)

Coherently explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Address how the proposed project, if successful, will have a major impact on the care of patients with cancer. Describe how this application provides a path for acquiring proof-of-principle data necessary for next-stage commercial development. Clearly explain the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.4.4. Goals and Objectives (maximum of 1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. Identify time-specific references as follows: Year 1, Quarter 1 (Y1Q1), Y1Q2, etc. Do not specify actual calendar dates as this can be confusing when dates change.

10.4.5. Timeline (1-page maximum)

Provide a visual depiction of anticipated major milestones to be tracked in the form of a Gantt chart. Identify time-specific references as follows: Y1Q1, Y1Q2, etc, as opposed to naming specific months and years. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is

approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

10.4.6. Resubmission Summary (1-page maximum)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application submitted or resubmitted before June 28, 2016, may be submitted as a new application, even if it was previously resubmitted. For the "new" applications, no summary is required.

10.4.7. Development Plan (12-page maximum)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. **Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims**. Outline the steps to be taken during the proposed period of the award, including the design of the translational and/or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches to these risks. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The development plan should include a defined **target product profile (TPP)** or analogous document for a medical device, in vitro diagnostic, or service that projects a clear path to full commercialization (see http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm080593.pdf). The TPP provides a statement of the *overall intent* of the product development program and gives information about the product *at a particular time* in development. Usually, the TPP is organized according to the key sections in the product package insert for a drug or

biologic or medical device labeling and links development activities to specific concepts intended for inclusion in the product labeling. CPRIT recognizes that many applications are early in the development process and that not all elements of the TPP will be known at the time of application. Consequently, not only does the TPP serve as a snapshot in time of the development status of the program, but it additionally serves as an aspirational target upon eventual commercialization. The TPP should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, medical device, diagnostic, or service that could be useful in the treatment of cancer?
- Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
- Description of a high-level clinical development plan detailing each of the clinical studies supporting marketing approval (phase 1, 2, and 3) the preclinical work is meant to support. Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the phase 1, phase 2, and phase 3 studies necessary to obtain regulatory approval and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Applicants developing cancer therapeutics are encouraged to become familiar with FDA guidance documents for submission of applications related to new product development. These documents provide a standard framework for new drug submissions and biologic license applications to the FDA. Utilizing this framework helps ensure that the submission to CPRIT contains all relevant elements and is optimally organized.

Additionally, for therapeutics, the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or will the use of this new agent require a paradigm shift (more frequent or less frequent dosing,

new route or method of administration), and if so, what impact will it have on current standard of care?

Optimization of the lead to ensure desired characteristics, including, but not limited to, the following studies:

- Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced
- Absorption, distribution, metabolism, excretion, including, but not limited to, relevant studies based on route of administration
- Safety (studies as mandated by ICH guidelines)
- Biomarkers (assays) that potentially target specific patient populations for clinical trials
- Biomarkers (assays) that can serve as potential pharmacodynamic markers of clinical activity during early clinical trials designed to demonstrate proof of concept
- Proposed current good manufacturing practice (including estimated costs) that can be scalable from phase 1 through phase 2. Include information on whether there are plans for possible formulation.

The FDA's website provides "Common Technical Documents" (CTDs, see http://www.ich.org/products/ctd.html) guidance documents. There are 3 CTDs covering safety, efficacy, and quality. This guidance presents a standard format for the preparation of a well-structured application. Applicants may condense or summarize the CTD format as they deem appropriate to meet page limitations.

While originally intended for regulatory authorities, these formats are also applicable for a CPRIT application. Many of our reviewers have extensive pharmaceutical development expertise and are familiar with these standard formats. Hence, utilizing the CTD format will simplify the review and ensure that the application contains all the relevant elements.

CPRIT recognizes that many applications are early in the product development process. Hence, not all elements of the CTD will be known at time of CPRIT application. We encourage applicants to complete as much of the Safety and Efficacy CTD sections as possible and to follow the submission format prescribed.

References for the Development Plan section should be provided as a stand-alone document that will be separately uploaded into CARS. In the interests of brevity include only the most pertinent

and current literature. While references will not count toward the Development Plan section page limit, it is essential to be concise and to select only those references relevant to the development plan. **Do not use the references to circumvent Development Plan section page limits by including data analysis or other nonbibliographic material.**

The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. Please avoid redundancy!

10.4.8. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies typically need to raise substantial funds from private sources to fully fund development. Hence, we require companies to provide a business plan that summarizes the rationale for investing in this project. Private investors will seek a financial return on their investment. They will need to be convinced that this project has high investment return potential based on its risk profile. They typically focus on market opportunity size, development path, and key risk issues.

Successful applicants will provide thoughtful, careful, and succinct rationale explaining why this program is an appropriate investment of CPRIT and private funds. Note that if the company is selected to undergo due diligence, additional information to support the application will be requested at that time. Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

Please provide an overview of the business rationale for investing in this project. The business rationale overview will be 2 pages maximum. In addition, please provide summaries of the following 9 key development issues with a maximum of 1 page each.

1. **Product and Market:** Provide an overview of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc. Information

on patient populations and market segments is helpful.

2. **Competition and Value Proposition:** Provide an overview of the competitive environment (current and future) and how the envisioned product will compete in the marketplace. Provide information on how the clinical utility (efficacy, safety, cost, etc) of this therapy compares with current and potential future therapies. A clear delineation of competitive advantages and data demonstrating these advantages are helpful.
3. **Clinical and Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities and the regulatory pathway for major markets. Please describe how this is driven by interactions with the FDA, if possible. The regulatory plan should include regulatory communications (including all interactions to date with the FDA) and strategy, with clarity provided on regulatory matters and current regulatory strategies.
4. **Pricing and Reimbursement:** Provide an overview of the product cost and anticipated revenue. Cost, price, and reimbursement references from similar products are helpful. An overview of how the company plans to obtain CMS and private insurance reimbursement approval is also helpful.
5. **Commercial Strategy:** Provide an overview of your financial projections and how you will generate a return on this investment. Describe how the company plans to bring the product to market. Information on physicians to be targeted, sales channels, etc, is helpful. Alternatively, many drugs are acquired by large pharma firms in the late development stages. If the company plans to seek acquisition, please provide an overview of similar transactions.
6. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated. Key risk issues typically include efficacy versus competitors, toxicity, clinical trials, FDA approval, dosage and delivery, CMC synthesis, changing competitive environment, etc.
7. **Funding to Date:** Provide an overview of the funding received, including a list of funding sources and a comprehensive capitalization table that should comprise all parties who have investments, stock, or rights in the company. A template

exemplifying an appropriate capitalization table is provided among the application materials. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.

8. **Intellectual Property:** Provide a concise discussion of the IP issues related to the project. List any relevant issued patents and patent applications. Please include the titles and dates the patents were issued/filed/published. List any licensing agreements that the company has signed that are relevant to this application.

9. **Key Personnel Located in Texas and Any Key Management Located Outside of Texas:** For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Key personnel are the Principal Investigator/Project Director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way. *Substantive* means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. *Measurable* means that they devote a specified percentage of time to the project. The indicated time is an obligatory commitment, regardless of whether or not they request salaries or compensation. "Zero percent" effort or "TBD" or "as needed" are not acceptable levels of involvement for those designated as key personnel. While all participants that meet these criteria should be identified as "key," it is expected that the number of key personnel will be kept to a minimum.

The entire Business Plan section shall typically comprise a maximum of 11 pages: a 2-page overview and nine, 1-page key issue summaries. Please avoid redundancy. Note that the section "Funding to Date" above may exceed this 1-page limit if necessary.

10.4.9. Biographical Sketches of Key Scientific Personnel (8-page maximum)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. You may use the "Product Development Research Programs: Biographical Sketch" template but are not required to do so.

(In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 10.4.8]).

10.4.10. Budget

In preparing the requested budget, applicants should be aware of the following:

- Each award mechanism allows for up to a 3-year funding program with an opportunity for extension after the term expires. **The budget must be aligned with the proposed milestones.** Financial support will be awarded based upon the breadth and nature of the project proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.
- CPRIT considers equipment to be items having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. If awarded, management of your grant will be facilitated if specific equipment is clearly identified in the application using plain language. **Equipment not listed in the applicant's budget must be specifically approved by CPRIT subsequent to the award contract**.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.
- The total amount of CPRIT funds allowed for an annual salary of an individual for FY 2019 is $200,000. In other words, an individual may request salary proportional to the percentage effort up to a maximum of $200,000. Salary amounts in excess of this limit must be paid from matching funds. Salary does not include fringe benefits. CPRIT FY 2019 is from September 1, 2018, through August 31, 2019.

  Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of $200,000. The salary cap may be revised at CPRIT's discretion.

The Budget section is composed of 4 subtabs that must be completed:

A. **Budget for All Project Personnel:** Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project.

B. **Detailed Budget for Year 1:** This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Consultant Charges, Contractual (Subaward/Consortium), Research Related, or Other. Applicants will be required to itemize costs.

C. **Budget for Entire Proposed Period of Performance:** This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs for all subsequent years. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*.

D. **Budget Justification:** Please specify your CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds. Please specify each line item from your CPRIT budget as well as other funds (including matching funds). Provide a compelling justification for the budget for each line item of the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. **If travel costs will include out-of-state or international travel, make that clear here.** The budget must be aligned with the proposed milestones.

11. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal

monitoring, and terms relating to revenue sharing and IP rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

Project Revenue Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement, which can be found at www.cprit.texas.gov and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has appropriate matching funds. For companies receiving an initial CPRIT award, the company must contribute $1.00 in matching funds for every $2.00 awarded by CPRIT. CPRIT reserves the right to seek a higher matching funds contribution, ie, the company will contribute $1.00 in matching funds for every $1.00 awarded by CPRIT, from a company that has already received a CPRIT award and is approved for a second award. Matching funds need not be in hand when the application is submitted, nor does the entire amount of matching funds for the full 3 years of the project need to be available at the start of the grant. However, the

appropriate amount of matching funds for each specific tranche must be obtained before each tranche of CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. **Before contacting the helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. In addition, for Frequently Asked Programmatic Questions, please go here and for Frequently Asked Technical Questions, please go here.**

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146 (toll free in United States only)
Email: Help@CPRITGrants.org

13.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Product Development Research Program Senior Manager.

Tel: 512-305-7676
Email: Help@CPRITGrants.org
Website: **www.cprit.texas.gov**

14. APPENDIX

14.1. Reviewer Evaluation Guidelines for Therapeutics

Primary Review Criteria (Scored)

Unmet medical need: Target Product Profile (TPP)

- Assuming successful accomplishment of development objectives, as reflected in the target product profile, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Target Validation

- If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
- Has engagement of the target with the agent been demonstrated by biochemical assay? What is the potency of the agent?
- Are there validated downstream pharmacodynamic (PD) markers of target modulation? How extensive is the in vitro evidence for expected PD effects? Has the agent shown biologically significant modulation of the target in vivo, especially in tumor tissue?
- Is the target uniquely or substantially overexpressed by tumor versus normal cells?
- Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
- Has the company's demonstration of target validation been externally/independently confirmed?
- Are there known mechanisms of resistance to the modulation of this target? If so, has the company proposed possible mitigation/preemptive approaches, such as combination chemotherapy?

Preclinical Characterization: Efficacy Proof of Concept

- Considering in vivo preclinical efficacy characterization and the patient populations or subpopulation(s) representing the initial clinical indication(s) for the drug, what is the

clinical relevance of the preclinical models? To elaborate, were in vivo/xenograft studies carried out in cell line-based models or PDX-derived models? In how many such models have studies been carried out? To what extent do these models reflect standard of care (SOC) for refractory versus drug-naive tumors? At the time of treatment initiation, were tumors established and measurable, or was treatment initiated shortly after tumor inoculation?

- Was antitumor activity predominantly growth inhibition or tumor regression? Were sustained complete remissions or "cures" achieved in the majority of animals and models? Were comparisons with optimally dosed SOC agents made? Where the agent is intended to be added to the SOC, is there compelling evidence of in vitro/in vivo synergy with SOC agents?
- Have results of preclinical efficacy studies carried out by the company been externally/independently confirmed?
- Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
- How strongly does the preclinical efficacy profile support the clinical efficacy expectations reflected in the TPP?

Preclinical Characterization: Safety

- How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
- Has the agent undergone CEREP-type screening for interactions with targets with known safety liabilities, eg, CYP 450, hERG?
- Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
- Can exposures associated with substantial antitumor efficacy/PD effects be achieved safely in vivo?
- Do preclinical pharmacokinetics (PK) studies indicate potential for clinical safety issues, eg, accumulation, variability, lack of dose proportionality?
- Have PK/PD issues been investigated with alternate dosing schedules in order to optimize the therapeutic index of the agent?
- Are there any issues with the distribution or metabolism of the agent?

- Overall, are results of safety characterization carried out so far such that the agent can be considered reasonably derisked from a safety perspective, or are there red flags? Alternatively, is the extent of preclinical safety characterization carried out so far insufficient to address this question?

Pharmaceutical Properties/Chemistry and Pharmacy

- In the case of agents intended for oral absorption, are there any issues with water solubility? Do formulation studies indicate the feasibility of oral administration?
- Were Lipinski-type criteria applied during the lead optimization process such that the lead compound has demonstrated properties that make it likely to be an orally active drug in humans?
- Are there any issues with the stability of the drug substance or the drug product?
- Is there scope for further lead optimization through structure-activity studies?
- In the case of biologicals, has a high-quality cell line been developed yet? Are yields acceptable? Does the purification process appear reasonable and scalable?
- Have analytical methods been adequately developed?
- Has the (lead) protein been adequately characterized biochemically, immunogenetically, and biophysically? Has absence of aggregate formation been demonstrated in stability studies?

Development Plan/Regulatory Aspects

- Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
- Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions (United States/European Union)? Do development proposals reflect specific regulatory authority input; eg, from pre-IND interactions? Alternatively, has regulatory authority interaction been insufficient so far?
- In the case of clinical studies, are patient populations adequately described and consistent with those representing the initial target indication(s)?
- Are efficacy end points appropriate for study designs? Is the sample size statistically adequately justified in terms of the target effect size?

- In the case of potentially pivotal clinical trials, moreover, are the proposed primary efficacy end points and target effect sizes consistent with regulatory precedence?
- Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
- Has the applicant demonstrated reasonable diligence in researching patient availability, competitive clinical trial activity, and recruitment issues such that patient enrollment projections can be considered realistic?
- Will the proposed programs advance development of the agent to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding?
- Are development milestones clear and adequately described? Is the overall project timeline realistic?

Competitive Analysis

- Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the agent compared to clinically relevant competitive products, including potentially competitive agents in development?
- Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable, considering the preclinical efficacy and safety data on the agent generated so far?

Intellectual Property/Freedom to Operate

- Have IP and freedom-to-operate aspects been addressed in the application?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate?

Chemistry, Manufacturing, and Controls (CMC)

- How advanced is CMC and manufacturing development?
- Are there any sourcing issues?

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- Are there significant technical difficulties within CMC/manufacturing scale up still to be addressed?

Business/Commercial Aspects

- Does the applicant need to raise further funds for the CPRIT matching requirement? In this case, how realistic are the applicant's assumptions about a successful fund-raising campaign? Does the applicant have a track record of success in raising development funding?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program of studies reasonably support such expectations?
- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and CMC/manufacturing? If not, are there plans to address such deficiencies?
- Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

14.2. Reviewer Evaluation Guidelines for Medical Devices and Diagnostics

Primary Review Criteria (Scored)

Product Validation

- Technical Validation: Has the product or technology been successfully validated, ie, prototyped, built and tested in ex vivo, animal, or clinical setting?
- Have biological proof of principle and product mechanism of action been demonstrated?
- Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
- Clinical Validation: Are clinical trials required to demonstrate product performance? If so, have they been planned or conducted?
- Biological Risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

Production/Manufacturing

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- How advanced is manufacturing development?
- Are there any sourcing issues?

Intellectual Property/Freedom to Operate

- Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique knowhow, etc?
- Does the company have issued patents? If not, have they conducted freedom to operate and patentability analysis?
- Considering patent type (Composition of Matter/ Formulation/Manufacturing Process/Use), and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate, if required?

Market Opportunity

- Does the product address a clearly defined unmet need; lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?

- Are target indication and market clearly defined?
- Is channel to market available? Does the company understand the entire value chain and all constituencies involved in procuring and utilizing the product?
- Does the company understand the clinical pathway that leads to utilizing the product?
- Is market opportunity of significant size and lucrative enough to justify investment?
- Has the applicant demonstrated time or cost savings?
- How does product fit with existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

Competition

- Is this a "Whole Product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
- Is value proposition clearly delineated, ie, improve efficacy, improve safety, reduce cost, or improve convenience)?
- Has the company demonstrated its value proposition versus competition?
- Has the company conducted a competitive analysis? Does it provide a comprehensive, realistic assessment of strengths and weakness versus competition based on the data generated to date?

Development Plan

- Have a comprehensive development plan and market entry strategy been developed? How realistic are these plans?
- Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

Management and Staffing

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in house personnel in such key areas as product engineering, clinical development, regulatory affairs, manufacturing, etc? If not, are there plans to address such deficiencies?

- Has the applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Financial Plan

- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?
- Has the company clearly anticipated pricing strategy and reimbursement environment?
- Is the projected return on investment congruent with investment opportunity and risks?

Funding

- Is investor interest in this sector sufficient to fund the company through profitability?
- Does the applicant already have available funds to meet the CPRIT matching requirement, or do they need to raise additional funds? In this case, how realistic are assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Have likely acquirers been identified by the applicant?
- Does the company have the resources to support required activities while fundraising?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program reasonably support such expectations?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Does the applicant demonstrate an understanding of the Texas spending requirement for CPRIT funds?

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
2019 Cycle 1 19.1 Product Development Panel-1 Meeting
(19.1-PDR_PDP-1)
Observation Report

Report No.	09-24-18_19.1-PDR_PDP-1
Program Name:	Product Development Research
Panel Name:	2019 Cycle 1 19.1 Product Development Panel-1 Meeting (19.1-PDR_PDP-1)
Panel Date:	9/24/2018
Report Date:	9/26/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 2019 Cycle 1 19.1 Product Development Panel-1 meeting. The meeting was chaired by Jack Geltosky and conducted via teleconference on September 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observer(s) noted the following during the meeting:

- Number (#) of applications: 15 applications were discussed and 5 applications were not discussed
- Panelists: One (1) panel chair and Ten (10) expert reviewers and Two (2) advocate reviewers
- ICON employees: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to clarifying policies, and answering procedural questions

There were two (2) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

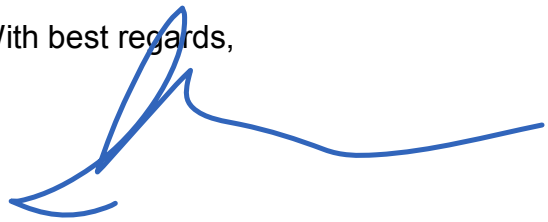
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
2019 Cycle 1 19.1 Product Development Panel-2 Meeting
(19.1-PDR_PDP-2)
Observation Report

Report No.	2018-09-25_19.1-PDR_PDP-2
Program Name:	Product Development Research
Panel Name:	2019 Cycle 1 19.1 Product Development Panel-2 Meeting (19.1-PDR_PDP-2)
Panel Date:	9/25/2018
Report Date:	9/27/2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 2019 Cycle 1 19.1 Product Development Panel-2 meeting. The meeting was chaired by David Shoemaker and conducted via teleconference on September 25, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observer(s) noted the following during the meeting:

- Number (#) of applications: Eleven (11) applications were discussed and seven (7) were not discussed
- Panelists: One (1) panel chair and eleven (11) expert reviewers and two (2) advocate reviewers
- ICON employees: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

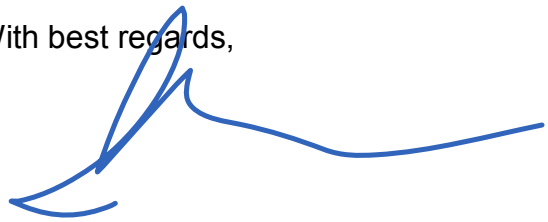
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Panel-1 Peer Review Meeting
(19.1_PDP-1)
Observation Report

Report No.	2018-10-23 19.1_PDP-1
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Panel-1 Peer Review Meeting (19.1_PDP-1)
Panel Date:	10-23/24-2018
Report Date:	10-30-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Panel-1 Peer Review (19.1_PDP-1) meeting. The meeting was chaired by Jack Geltosky and conducted via in-person in Dallas, Texas on October 23 and 24, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and Ten (10) were not discussed
- Panelists: One (1) panel chair and twelve (12) expert reviewers and two (2) advocate reviewers
- ICON employees: Two (2)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and four (4) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

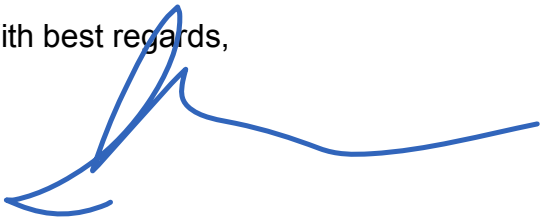
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Panel-2 Peer Review Meeting
(19.1_PDP-2)
Observation Report

Report No.	2018-10-25 19.1_PDP-2
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Panel-2 Peer Review Meeting (19.1_PDP-2)
Panel Date:	10-25/26-2018
Report Date:	10-30-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Panel-2 Peer Review (19.1_PDP-2) meeting. The meeting was chaired by David Shoemaker and conducted via in-person in Dallas, Texas on October 25 and 26, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and eleven (11) were not discussed
- Panelists: One (1) panel chair and fourteen (14) expert reviewers and two (2) advocate reviewers
- ICON employees: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) and three (3) additional GDIT or contract staff participated intermittently in a technical or logistics support role;
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were eight (8) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

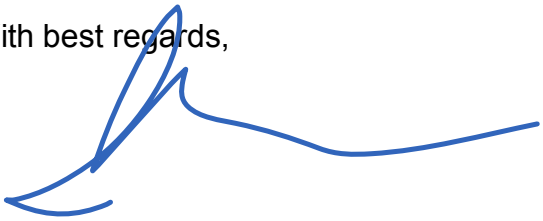
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part - 1 Meeting
(19.1_PDR_DD_P-1)
Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-1
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 1 Meeting (19.1_PDR_DD_P-1)
Panel Date:	01-11-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 1 Meeting (19.1_PDR_DD_P-1). The meeting did not have an assigned chair; the duties were performed by David Shoemaker and conducted via teleconference on January 11, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: Ten (10) expert reviewers
- ICON employees: Six (6)
- IP Attorneys: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

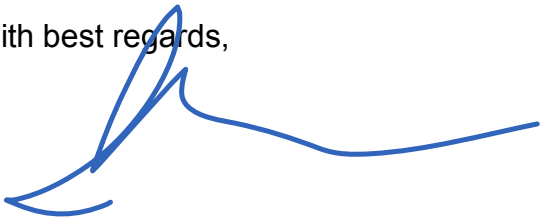
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part - 2 Meeting
(19.1_PDR_DD_P-2)
Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-2
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 2 Meeting (19.1_PDR_DD_P-2)
Panel Date:	01-14-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 2 Meeting (19.1_PDR_DD_P-2). The meeting did not have an assigned chair; the duties were performed by Jack Geltosky and conducted via teleconference on January 14, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: Eight (8) expert reviewers
- ICON employees: Six (6)
- IP Attorneys: Three (3)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

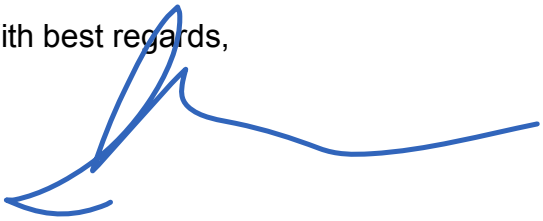
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
19.1 Product Development Due Diligence Part – 2 Continuation Meeting (19.1_PDR_DD_P-2 con.) Observation Report

Report No.	2019-01-11 PRD_DD_19.1_P-2 Continuation
Program Name:	Product Development Research
Panel Name:	19.1 Product Development Due Diligence Part - 2 Continuation Meeting (19.1_PDR_DD_P-2 Con.)
Panel Date:	01-22-2019
Report Date:	01-23-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 19.1 Product Development Due Diligence Part - 2 Continutation Meeting (19.1_PDR_DD_P-2 Con.). The meeting did not have an assigned chair; the duties were performed by Jack Geltosky and conducted via teleconference on January 22, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observer(s) participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: Six (6) expert reviewers
- ICON employees: Zero (0)
- IP Attorneys: Zero (0)
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

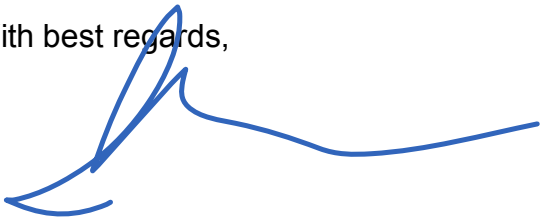
In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed

additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
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cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Product Development Research Applications
(Product Development Research Cycle 19.1 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 19.1 include *Company Relocation Product Development Awards, Seed Awards for Product Development Research,* and *Texas Company Product Development Awards.* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
DP190027	Piers Ingram	Hummingbird Bioscience Pte Ltd	V. Lee
DP190021	Kurt Gunter	Cell Medica	G. Williams;L. Greenberger
Applications not considered by the PIC or Oversight Committee			
DP190028	Laura Indolfi	PanTher Therapeutics, Inc	V. Lee
DP190035	Patrick Rivelli	Savran Technologies, Inc.	G. Cipau
DP190043*	Tania Fernandez	Midissia Therapeutics	H. Lyerly;V. Lee
DP190046	Mustapha Haddach	Pimera, Inc.	V. Lee
DP190047*	Sam Shrivastava	Venn Therapeutics, LLC	V. Lee
DP190060*	David Conway	Terra Biological LLC	V. Lee

High Level Summary of Due Diligence

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommends that the Program Integration Committee and the Oversight Committee approve the following Texas Company Product Development Research grant awards:

- Cell Medica for $8,742,509. The PDRC recommended contract contingencies for this award.

Cell Medica

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

The proposed $8,742,509 award to Cell Medica, Inc. supports the development of a novel off-the-shelf chimeric antigen receptor (CAR) natural killer T cell (NKT) therapy. Cell Medica's novel approach uses healthy donor immune cells (off-the-shelf) modified to treat a variety of incurable tumors. The proposed CPRIT grant will support Phase 1 and 2 clinical studies conducted at Baylor College of Medicine and other Texas institutions to advance this novel therapy into humans. Cell Medica also proposes to develop new CAR NKT products for additional indications at their Houston facility.

One reviewer summarized the significance and impact as follows: *This project, if successful, would provide a useful option for certain cancers, with a similar but simultaneously slightly different approach from the plethora of existing approved treatments and those in the pipeline. The applicant is a solid and collaborative endeavor and will be drawing on 2 previously funded CPRIT grants. This applicant is well funded, and the investment by CPRIT would not even be for one-half of the cost of the project. This application will move the off-the-shelf CART product development farther along. If successful, given the plethora of other companies in the similar space, it is quite possible that another company would want to acquire the company or the product and continue with the necessary phase 2and 3studies and get it to market.*

De-Identified Overall Evaluation Scores

Texas Company Product Development Awards

Product Development Research Cycle 19.1

As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

Application ID	Final Overall Evaluation Score
wa	3.0
DP190021*	3.1
Wb	3.1
Wc	4.3
Wd	4.3
We	5.3

* Recommended for award

Final Overall Evaluation Scores and Rank Order Scores

January 23, 2019

Will Montgomery
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com
Via email to Will Montgomery's assistant, Laura Blevins, lblevins@jw.com

Wayne R. Roberts
Program Integration Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Will and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 19.1 grant award cycle.

The PDRC recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Hummingbird Bioscience, Allterum Therapeutics, Cell Medica, Icell Kealex Therapeutics and Instapath. The attached table reflects the ranked award recommendations, including the maximum recommended funding amounts and the overall evaluation scores for the five grant applications.

The PDRC did not make any changes to the goals, timelines, or budgets for the five projects recommended for funding. However, three of these recommendations are contingent on the review of the items described as follows:

- Execution of the CPRIT award contract for Allterum Therapeutics is contingent on the company's completion of the license agreement with the National Cancer Institute and CPRIT's review of documentation associated with the University of Maryland licensing agreement as outlined in the Vinson & Elkins IP Memorandum.
- Execution of the CPRIT award contract for Cell Medica is contingent on the company's completion of the recommendations set forth in the Vinson & Elkins IP Memorandum regarding patent coverage.
- Execution of the CPRIT award contract for Icell Kealex Therapeutics is contingent on resolution of the IP and licensing issues as outlined in the IP Diligence Memorandum from Baker Botts LLP.

The PDRC did not identify any contingencies associated with the awards to Hummingbird Bioscience or Instapath.

Each of companies included in the PDRC's recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PDRC's review of the due

diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

I will also note that the PDRC elected to take no action on two pending applications considered during due diligence review. Additional information is needed from the applicants before making final award decisions on DP190041 and DP190046. Once the applicants provide the requested information, the PDRC will reconvene and evaluate the data before making final award decisions. We anticipate that we will provide our award recommendations, if any, regarding these two pending proposals for consideration at either the May or August Oversight Committee meeting.

Sincerely,

/JG/ J Deltosky

Jack Geltosky, PhD

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations

FY 2019, Cycle 1

Rank	Application ID	Mech.	Company Name	Project	Maximum Recommended Budget	Overall Score
1	DP190027	RELCO	Hummingbird Bioscience Pte Ltd	A First-in-Class Anti-VISTA Monoclonal Antibody for the Treatment of MDSC-Mediated Suppression of Antitumor Immunity in Solid Tumors and Lymphomas	$13,116,095	2.0
2	DP190025	SEED	Allterum Therapeutics, LLC	Preclinical Development of a Novel T-ALL Therapeutic Antibody	$2,912,313	2.2
3	DP190020	SEED	Icell Kealex Therapeutics LLC	Development of a Novel Oncolytic Vaccinia Virus Variant Suitable for Systemic Delivery	$3,000,000	2.5
4	DP190021	TXCO	Cell Medica	Off-the-Shelf CAR-NKT Cells for Treatment of Solid and Hematological Malignancy	$8,742,509	3.1
5	DP190018	RELCO	Instapath Inc.	Rapid Pathology Evaluation System for Biopsies	$3,000,000	2.2
				Total	$30,770,917	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycles 4-6
Recruitment of First-Time, Tenure-Track Faculty Members

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | www.cprit.state.tx.us

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-19.1-RFT

Recruitment of First-Time Tenure-Track Faculty Members

Please also refer to the Instructions for Applicants document, which will be posted on June 21, 2018

Application Receipt Dates:

June 21, 2018-June 20, 2019

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 6/21/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions
- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract very promising investigators who are pursuing their first faculty appointment at the level of assistant professor (first-time, tenure-track faculty members). These individuals must have demonstrated academic excellence, innovation during predoctoral and/or postdoctoral research training, commitment to pursuing cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. However, special consideration will be given to candidates with research programs addressing CPRIT's priority areas for research. These include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions computational biology and analytic methods, childhood cancers, and hepatocellular cancer.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. All candidates are expected to have completed their doctoral and fellowship training and to have clearly demonstrated truly superior ability as evidenced by their accomplishments during training, proposed research plan, publication record, and letters of recommendation. This CPRIT-supported initiative is designed to enhance innovative programs of excellence by providing research support for promising, early-stage investigators **seeking their first tenure-track position.**

CPRIT will provide start-up funding for newly independent investigators, with the goal of augmenting and expanding the institution's efforts in cancer research. Candidates will be expected to develop research projects within the sponsoring institution. Projects should be

appropriate for a newly independent investigator and should foster the development of preliminary data that can be used to prepare applications for future independent research project grants to further both the investigator's research career and the CPRIT mission. The institution will be expected to work with each newly recruited research faculty member to design and execute a faculty career development plan consistent with his or her research emphasis. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. INSTITUTIONAL COMMITMENT

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a First-Time Tenure-Track Faculty should therefore be complemented by a strong institutional commitment to the candidate's career development that includes financial commitments that are in addition to the CPRIT award. The institutional commitment should be clearly documented in the application (see section 8.2.2) and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate for his or her research program by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT Award.

5. FUNDING INFORMATION

This award is up to 5 years and is not renewable, although individuals may apply for other future CPRIT funding as appropriate. Grant funds of up to $2,000,000 (total costs) for the 5-year period may be requested. Funding is to be used by the candidate to support his or her research program. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the

year. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified.

Funds from this CPRIT award may not be used for salary support of this candidate or to construct or renovate laboratory space. No annual limit on the number of potential award recipients has been set.

Note: Depending on the availability of funds, nominations submitted in response to this Request for Applications (RFA) during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31, 2019) or in the first quarter of the next fiscal year (starting September 1, 2019).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made. There is no limit to the number of applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position as assistant professor tenure track at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating institution of the Scientific Review Council's review decision following the Scientific

Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.

- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate must ***not*** hold an appointment at the rank of assistant professor or above (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. Candidates holding non-tenure-track appointments at the rank of assistant professor are ***not*** eligible for this award. Examples of such appointments include research assistant professor, adjunct research assistant professor, assistant professor (non-tenure track). The candidate may or may not reside in Texas at the time the application is submitted and may be nominated for a faculty position at the Texas institution where he or she is completing postdoctoral training.
- Successful candidates will be offered tenure-track academic positions at the rank of assistant professor.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in

a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of First-Time, Tenure-Track Faculty Members award mechanism. Any nomination for the Recruitment of First-Time, Tenure-Track Faculty Members that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (Nominator) must create a user account in the system to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants

Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Applications will be accepted on a continuous basis throughout FY19. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 PM central time. In the event that the 20th falls on Saturday or Sunday, applications may be submitted on or before 11:59 PM central time the following Monday. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. For details, please refer to the *Instructions for Applicants* document that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 6 will be administratively withdrawn without review.

8.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a First-Time Tenure-Track Faculty should therefore be complemented by a strongly documented institutional commitment to the candidate's career development that includes financial commitments that are in addition to the CPRIT award.

The institutional commitment should be clearly documented in the application in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

NOTE: INSTITUTIONAL COMMITMENT AS DESCRIBED ABOVE MUST BE INCLUDED IN THE GRANT APPLICATION, PRESENTED IN A TABULAR SUMMARY THAT CLEARLY IDENTIFIES THE SALARY AMOUNT, SOURCES, AND ANY ADDITIONAL RESEARCH SUPPORT FROM INSTITUTIONAL SOURCES OVER THE COURSE OF THE CPRIT AWARD.

The following guidelines should be used when documenting the institutional commitment in the letter signed by the applicant institution's president, provost, or appropriate dean.

1. Demonstrate the organization's commitment to bringing the candidate to Texas.
2. State the total award amount requested.
3. Include a brief job description for the candidate should recruitment be successful.
4. Clearly describe the institutional commitment to the candidate including total salary and fringe benefits and sources of salary support through the course of the CPRIT award; additional financial support for the applicant's research program including dedicated personnel, access to students, amounts for equipment and supplies; space assignment and access to shared equipment; and all other agreements between the institution and the candidate.
5. This information is required to be provided as a tabular summary that states the approximate amounts assigned to each item.
6. Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is encouraged when proposing a candidate with exceptional expertise and/or talent that can be

directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.

Note that Texas law allows an institution of higher learning to use a federal indirect cost rate credit to comply with the requirement to demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award (see section 12). However, a federal indirect cost rate credit should not be used to demonstrate an institutional commitment to the candidate.

8.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research: While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

The letter of support from the department chair must also do the following:

1. Describe how the candidate will be independent and autonomous in developing his or her research program at the institution;
2. Present a plan for mentoring that includes the design and execution of a faculty career development plan for the candidate.

8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate. Only articles that have been published or that have been accepted for publication ("in press") should be cited.

8.2.5. Summary of Goals and Objectives (2,000 characters)

List very broad goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.**

"I understand that I do not need to have made a commitment to <*nominating institution*> before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are inappropriate."

8.2.7. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2 page synergy plan (see IFA).

8.2.8. Publications

Provide the 3 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

8.2.9. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.10. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.11. Letters of Recommendation

Provide 3 letters of recommendation from individuals who are in a position to detail the candidate's academic and scientific research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research.

8.2.12. Research Environment (1 page)

Clearly and concisely describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

8.2.13. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award. **This section of the application must be prepared by the candidate.** If the application is approved for funding, this section will be made publicly available on CPRIT's website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components; exceed the specified page, word, or budget limits; or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

9. APPLICATION REVIEW

9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

9.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of the Department of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. **Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution.**

It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have reasonable expectation that the recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his or her proposed research program, and his or her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated academic excellence? Has the candidate received excellent predoctoral and postdoctoral training? Does the candidate show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated a commitment to cancer research? Has the candidate demonstrated independence or the potential for independence?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will the proposed research generate preliminary data that can be used for the preparation of applications for future independent research project grants?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Letters of Recommendation: Do the letters of recommendation detail the candidate's academic and clinical research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on growing his or her research? Has the institution identified a mentor who will design and execute a faculty career development plan for the candidate?

10. KEY DATES

RFA

RFA Release June 21, 2018

Application Receipt and Review Timeline

Application Receipt System opens 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 21, 2018	Continuous	Monthly by the 15th day of the month	June 20, 2019

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding the demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Academic Research.

Tel: 512-305-8491
Email: Help@CPRITGrants.org
Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Recruitment Review Panel-19.4-5 Peer Review Meeting (REC_19.4-5)
Observation Report

Report No.	2018-12-18 REC_19.4-5
Program Name:	Academic Research
Panel Name:	Recruitment Review Panel-19.4-5 Peer Review Meeting (REC_19.4-5)
Panel Date:	12-13-2018
Report Date:	12-13-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel-19.4-5 Peer Review Meeting (REC_19.4-5) meeting. The meeting was chaired by Richard Kolodner and conducted via teleconference on December 13, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed
- Panelists: One (1) panel chair and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (x)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

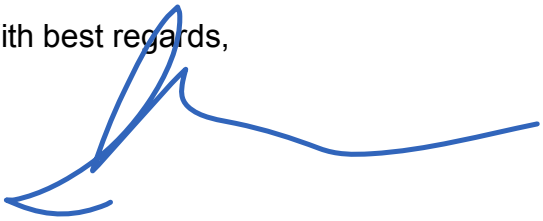
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Recruitment Review Panel-19.6 Peer Review Meeting
(REC_19.6)
Observation Report

Report No.	2019-01-17 REC_19.6
Program Name:	Academic Research
Panel Name:	Recruitment Review Panel-19.6 Peer Review Meeting (REC_19.6)
Panel Date:	01-17-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel-19.6 Peer Review Meeting (REC_19.6) meeting. The meeting was chaired by Richard Kolodner and conducted via teleconference on January 17, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed
- Panelists: One (1) panel chair and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

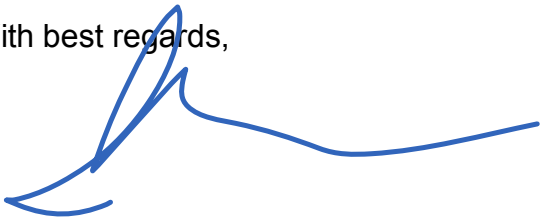
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Academic Research Recruitment 19.4-6 Applications
(Academic Research Recruitment Cycle 19.4-6 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 19.4-6 include *Recruitment of Established Investigators, Recruitment of First-Time Tenure-Track Faculty Members, and Recruitment of Rising Stars*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
No conflicts reported.			
Applications not considered by the PIC or Oversight Committee			
No conflicts reported.			

De-Identified Overall Evaluation Scores

Recruitment of First-Time, Tenure-Track Faculty Members

Academic Research Recruitment Cycles 19.4-6

Application ID	Final Overall Evaluation Score
RR190023*	1.0
RR190025*	1.6
RR190020*	2.0
RR190029*	2.2
RR190021*	2.8
Qa	3.6
Qb	4.0

* Recommended for award

Final Overall Evaluation Scores and Rank Order Scores

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on December 13, 2018 (REC Cycles 19.4 and 19.5), and January 17, 2019 (REC Cycle 19.6) to consider the applications submitted to CPRIT under the Recruitment of Rising Stars and Recruitment of First-Time Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended for all cycles is $14,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Candidate	Mechanism	Organization	Budget	Overall Score
1	RR190023	Uri Ben-David, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	1.0
2	RR190025	Julian West, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	Rice University	$2,000,000	1.6
3	RR190020	Sangeetha Reddy, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.0
4	RR190027	Joshi Alumkal, M.D.	Recruitment of Rising Stars	The University of Texas Southwestern Medical Center	$4,000,000	2.0
5	RR190029	Ravikanth Maddipati, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.2
6	RR190021	Di Zhao, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	2.8

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2019—Cycles 4-6
Recruitment of Rising Stars

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-19.1-RRS

Recruitment of Rising Stars

Please also refer to the Instructions for Applicants document, which will be posted on June 21, 2018

Application Receipt Dates:

June 21, 2018-June 20, 2019

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 6/21/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions
- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract individuals whose work has outstanding merit, who show a marked capacity for self-direction, and who demonstrate the promise for continued and enhanced contributions to the field of cancer research ("Rising Stars"). Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas. The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. However, special consideration will be given to candidates with research programs addressing CPRIT's priority areas for research. These include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational biology and analytic methods, childhood cancers, and hepatocellular cancer.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. Having already demonstrated extraordinary accomplishments during their initial years of independent research, Rising Stars represent a unique blend of scholastic aptitude, scientific rigor, and commitment to exploring transformational research through the development of creative ideas with high potential.

Candidates who have not historically worked in cancer research but are proposing creative hypotheses and research plans for this field are encouraged to apply. Similarly, candidates pursuing original and potentially high-impact basic science programs that have the potential to be translated toward clinical investigations or provide "proof of principle" are also encouraged to apply. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving

outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates are expected to be approximately at the career level of a late assistant/early associate professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. INSTITUTIONAL COMMITMENT

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a Rising Star should be complemented by a strong institutional commitment to the recruitment (see section 8.2.2). The financial commitments made to the candidate by the recruiting institution is required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

5. FUNDING INFORMATION

This is a 5-year award and is not renewable. Grant funds of up to $4,000,000 (total costs) over a 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. Annual allocations of this award are at the discretion of the awardee, as long as the total award does not exceed $4,000,000. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years except under extraordinary circumstances with strong justification for a no

cost extension. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified.

Funds from this award mechanism may be used for salary support of this candidate but may not be used to construct or renovate laboratory space. No annual limit on the number of potential award recipients has been set.

Note the annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award for FY 2019 is limited to a maximum of $200,000. In other words, an individual may request salary proportional to the percent of effort up to a maximum of $200,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

Note: Depending on the availability of funds, nominations submitted in response to this Request for Applications (RFA) during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31, 2019) or in the first quarter of the next fiscal year (starting September 1, 2019).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.

- A candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating institution of the Scientific Review Council's review decision following the Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of assistant or associate professor tenure track or tenured (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. The candidate must not reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.

- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Rising Stars award mechanism. Any nomination for the Recruitment of Rising Stars that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (Nominator) must create a user account in the system to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants

Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Dependent upon available funding, applications will be accepted on a continuous basis throughout FY18. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 PM central time. In the event that the 20th falls on Saturday or Sunday, applications may be submitted on or before 11:59 PM central time the following Monday. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. For details, please refer to the *Instructions for Applicants* document that will be available when the application receipt system opens.

Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 6 will be administratively withdrawn without review.

8.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a Rising Star should be complemented by a strongly documented institutional commitment to the recruitment.The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

NOTE: INSTITUTIONAL COMMITMENT AS DESCRIBED ABOVE MUST BE INCLUDED IN THE GRANT APPLICATION, PRESENTED IN A TABULAR SUMMARY THAT CLEARLY IDENTIFIES THE SALARY AMOUNT, SOURCES, AND ANY ADDITIONAL RESEARCH SUPPORT FROM INSTITUTIONAL SOURCES OVER THE COURSE OF THE CPRIT AWARD.

The following guidelines should be used when outlining the institutional commitment:

1. Information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean.
2. The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas.
3. State the total award amount requested.
4. Include a brief job description for the candidate should recruitment be successful.
5. Clearly describe the institutional commitment to the candidate, including documentation of total salary, institutional salary support through the course of the CPRIT award and additional support for the applicant's research program, endowment or other support, space, equipment, and all other agreements between the institution and the candidate.
6. This information is required to be provided as a tabular summary that states the approximate amounts assigned to each item.
7. Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.

Note that Texas law allows an institution of higher learning to use a federal indirect cost rate credit to comply with the requirement to demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award (see section 12). However, a federal indirect cost rate credit should not be used to demonstrate an institutional commitment to the candidate.

8.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research: While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

8.2.5. Summary of Goals and Objectives (2,000 characters)

List very broad goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort, and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.** "I understand that I do not need to have made a commitment to <*nominating*

institution> before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are inappropriate."

8.2.7. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2 page synergy plan (see IFA).

8.2.8. Publications

Provide the 5 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

8.2.9. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.10. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.11. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

8.2.12. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award. **This section of the application must be prepared by the candidate.** If the application is approved for funding, this section will be made publicly available on CPRIT's website. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components; exceed the specified page, word, or budget limits; or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

9. APPLICATION REVIEW

9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

9.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of the Department of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely

to be successful unless there is a strong commitment from CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated extraordinary accomplishments during his or her initial years of independent research? Does the candidate show promise of making important contributions with significant impact to basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated strong self-direction, motivation, and commitment for transformative cancer research?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program? Will the candidate be provided with adequate professional development opportunities to grow as a leader?

10. KEY DATES

RFA

RFA Release June 21, 2018

Application Receipt and Review Timeline

Application Receipt System opens 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 21, 2018	Continuous – dependent upon available funding	Monthly by the 15th day of the month	June 20, 2019

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. **Continuation of funding is contingent upon the timely receipt of**

these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding the demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Academic Research.

Tel: 512-305-8491
Email: Help@CPRITGrants.org
Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
Recruitment Review Panel-19.4-5 Peer Review Meeting (REC_19.4-5)
Observation Report

Report No.	2018-12-18 REC_19.4-5
Program Name:	Academic Research
Panel Name:	Recruitment Review Panel-19.4-5 Peer Review Meeting (REC_19.4-5)
Panel Date:	12-13-2018
Report Date:	12-13-2018

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel-19.4-5 Peer Review Meeting (REC_19.4-5) meeting. The meeting was chaired by Richard Kolodner and conducted via teleconference on December 13, 2018.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed
- Panelists: One (1) panel chair and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (x)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

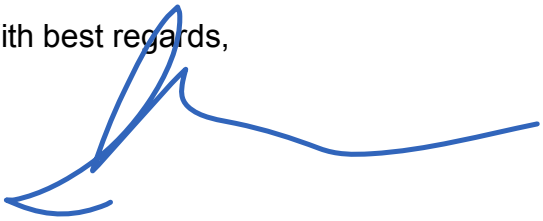
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
Recruitment Review Panel-19.6 Peer Review Meeting
(REC_19.6)
Observation Report

Report No.	2019-01-17 REC_19.6
Program Name:	Academic Research
Panel Name:	Recruitment Review Panel-19.6 Peer Review Meeting (REC_19.6)
Panel Date:	01-17-2019
Report Date:	01-17-2019

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the Recruitment Review Panel-19.6 Peer Review Meeting (REC_19.6) meeting. The meeting was chaired by Richard Kolodner and conducted via teleconference on January 17, 2019.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed
- Panelists: One (1) panel chair and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were zero (0) COIs identified prior to and/or during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict, respectively.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

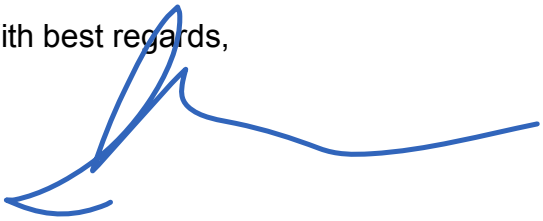
CONCLUSION

In conclusion; we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure
Academic Research Recruitment 19.4-6 Applications
(Academic Research Recruitment Cycle 19.4-6 Awards Announced at February 21, 2019, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 19.4-6 include *Recruitment of Established Investigators, Recruitment of First-Time Tenure-Track Faculty Members, and Recruitment of Rising Stars*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/PI	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
No conflicts reported.			
Applications not considered by the PIC or Oversight Committee			
No conflicts reported.			

De-Identified Overall Evaluation Scores

Recruitment of Rising Stars

Academic Research Recruitment Cycles 19.4-6

Application ID	Final Overall Evaluation Score
RR190027*	2.0

* Recommended for award

Final Overall Evaluation Scores and Rank Order Scores

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@ucsd.edu

San Diego Branch
UC San Diego School of Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

January 17, 2019

Mr. Will Montgomery
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to wsmcprit@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Montgomery and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on December 13, 2018 (REC Cycles 19.4 and 19.5), and January 17, 2019 (REC Cycle 19.6) to consider the applications submitted to CPRIT under the Recruitment of Rising Stars and Recruitment of First-Time Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended for all cycles is $14,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Candidate	Mechanism	Organization	Budget	Overall Score
1	RR190023	Uri Ben-David, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	1.0
2	RR190025	Julian West, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	Rice University	$2,000,000	1.6
3	RR190020	Sangeetha Reddy, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.0
4	RR190027	Joshi Alumkal, M.D.	Recruitment of Rising Stars	The University of Texas Southwestern Medical Center	$4,000,000	2.0
5	RR190029	Ravikanth Maddipati, M.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	2.2
6	RR190021	Di Zhao, Ph.D.	Recruitment of First-Time, Tenure Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000	2.8

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP190018
Seed Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Seed Awards for Product Development Research* Request for Applications (RFA). CPRIT received 27 applications in response to this RFA, including two applications that were withdrawn. This application was assigned to the product development panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

Due diligence review meetings spanned a three-day period—January 11, 14, and 22. The extended time period was due to the increased volume of applications that were recommended for due diligence. Additionally, in the PDRC recommendation letter sent to the PIC, three applications recommended by the PDRC were ranked ahead of an application with either an equal to or more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

CPRIT's newly hired Chief Product Development Officer, Cindy WalkerPeach, listened in on the meetings on January 11th and 14th. Prior to due diligence, she certified that she had no conflict of interest, as defined by CPRIT's statute and rules, with the applications that were discussed during due diligence review.

Pursuant to TAC § 702.19(e), I granted the Interim Chief Product Development Officer (CPDO) a waiver from the general prohibition on communication upon a finding that the waiver was in the best interest of the Institute and was not intended to give one applicant advantage over another. The Oversight Committee was notified of the waiver on February 8, 2019, in writing. The waiver allows the Interim CPDO to discuss equity issues with one of the companies.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:53 PM

FY:	2019
CYCLE:	1
PROGRAM:	Product Development
MECHANISM:	Seed Awards for Product Development Research
APPLICATION ID:	RP190018
APPLICATION TITLE	Rapid pathology evaluation system for biopsies
APPLICANT NAME:	Wang, Mei
ORGANIZATION:	Invenpath Inc.
PANEL NAME:	PDT Product Development Panel 1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA approved by CPDO	05/04/2018	12/11/2018
	RFA published in Texas.gov eGrants	05/17/2018	12/11/2018
	CPRIT Application Receipt System (CARS) opened	06/28/2018	12/11/2018
	CPRIT Application Receipt System (CARS) closed	08/08/2018	12/11/2018
	Date application submitted	08/08/2018	12/11/2018
	Method of submission	CARS	12/11/2018
	Within receipt period	YES	12/11/2018
	Request for extension to submit application after CARS closed	NA	12/12/2018
	Request for extension for late application submission accepted	NA	12/12/2018
	Submission of application fee	YES	01/31/2019
Receipt, Referral, and Assignment	Administrative review notification	08/24/2018	12/12/2018
	Donation(s) made to CPRIT / foundation	NO	12/12/2018
	Assigned to primary reviewers	08/30/2018	12/12/2018
	Applicant notified of review panel assignment	08/30/2018	12/12/2018
	Primary Reviewer 1 COI signed	08/27/2018	12/11/2018
	Primary (Advocate) Reviewer 2 COI signed	08/22/2018	12/11/2018
	Primary Reviewer 3 COI signed	08/24/2018	12/11/2018
	Primary Reviewer 4 COI signed	08/29/2018	12/11/2018
Screening Teleconference Meeting	Primary Reviewer 1 critique submitted	09/18/2018	12/11/2018
	Primary (Advocate) Reviewer 2 critique submitted	09/15/2018	12/11/2018
	Primary Reviewer 3 critique submitted	09/19/2018	12/11/2018
	Primary Reviewer 4 critique submitted	09/18/2018	12/11/2018
	COI indicated by non-primary reviewer	NONE	12/12/2018
	COI recused from participation	NA	12/12/2018
	Screening Teleconference Meeting	09/24/2018	12/12/2018
	Post Screening Teleconference score report	09/24/2018	12/12/2018
	Post review statements signed	10/27/2018	12/12/2018
	Third Party Observer Report	09/26/2018	12/11/2018
	Recommended for On-Site Meeting	YES	12/12/2018
Peer Review Meeting	COI indicated by non-primary reviewer	NONE	12/12/2018
	COI recused from participation	NA	12/12/2018
	Peer Review Meeting	10/23/2018	12/12/2018
	Peer Review Meeting End Date	10/24/2018	12/12/2018
	Post review statements signed	10/30/2018	12/12/2018
	Third Party Observer Report	10/30/2018	12/12/2018
	Score report delivered to CPDO	11/05/2018	12/12/2018
	Recommended for due diligence and IP review	YES	12/12/2018
Due Diligence and IP Review	Final due diligence review submitted to PDRC	01/02/2019	01/29/2019
	Intellectual Property conflict check	11/15/2018	01/29/2019
	Final intellectual property review submitted	01/02/2019	01/29/2019
Final PDRC Recommendation	COI indicated by PDRC member	NONE	01/22/2019
	COI recused from participation	NA	01/22/2019
	Due Diligence Evaluation Meeting / PDRC Meeting	01/14/2019	01/22/2019
	Third Party Observer Report	01/17/2019	01/22/2019
	Recommended for grant award	YES	01/22/2019
	PDRC Chair Notification to PIC and OC	01/23/2019	01/29/2019
	COI indicated by PDRC member (Ranking Meeting)	NONE	01/22/2019
	COI recused from participation (Ranking Meeting)	NA	01/22/2019
	PDRC Ranking Meeting	01/22/2019	01/22/2019
	Third Party Observer Report	01/23/2019	01/31/2019
	Recommended for grant award	YES	01/22/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP190020
Seed Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

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Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
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State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:53 PM

FY:	2019
CYCLE:	1
PROGRAM:	Product Development
MECHANISM:	Seed Awards for Product Development Research
APPLICATION ID:	DP190030
APPLICATION TITLE	Development of a Novel Oncolytic Vaccinia Virus Variant suitable for Systemic Deliver
APPLICANT NAME:	Tong, Meehong
ORGANIZATION:	Gulf Coast Therapeutics INC
PANEL NAME:	FY19 Product Development Panel 1

Category	Compliance Requirement	Information	Attestation Date
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	Recommended for grant award	YES	01/22/2019
	PDRC Chair Notification to PIC and OC	01/23/2019	01/29/2019
	COI indicated by PDRC member (Ranking Meeting)	NONE	01/22/2019
	COI recused from participation (Ranking Meeting)	NA	01/22/2019
	PDRC Ranking Meeting	01/22/2019	01/22/2019
	Third Party Observer Report	01/23/2019	01/31/2019
	Recommended for grant award	YES	01/22/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	COI Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI recused from participation	NA	
	Question(s) made to CPRIT / Foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP190021
Texas Company Product Development Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Texas Company Product Development Awards* Request for Applications (RFA). CPRIT received five applications in response to this RFA. This application was assigned to the product development panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

Due diligence review meetings spanned a three-day period—January 11, 14, and 22. The extended time period was due to the increased volume of applications that were recommended for due diligence. One application from this mechanism was recommended ahead of two applications with either the same or more favorable score. Additionally, in the PDRC recommendation letter sent to the PIC, three applications recommended by the PDRC were ranked ahead of an application with either an equal to or more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

CPRIT's newly hired Chief Product Development Officer, Cindy WalkerPeach, listened in on the meetings on January 11th and 14th. Prior to due diligence, she certified that she had no conflict of interest, as defined by CPRIT's statute and rules, with the applications that were discussed during due diligence review.

Pursuant to TAC § 702.19(e), I granted the Interim Chief Product Development Officer (CPDO) a waiver from the general prohibition on communication upon a finding that the waiver was in the best interest of the Institute and was not intended to give one applicant advantage over another. The Oversight Committee was notified of the waiver on February 8, 2019, in writing. The waiver allows the Interim CPDO to discuss equity issues with one of the companies.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:53 PM

FY:	2019
CYCLE:	I
PROGRAM:	Product Development
MECHANISM:	Texas Company Product Development Research Awards
APPLICATION ID:	RP190021
APPLICATION TITLE	Off the Shelf CAR-NET Cells for Treatment of Solid and Hematological Malignancy
APPLICANT NAME:	Hunter, Ewie E
ORGANIZATION:	Cell Medica
PANEL NAME:	19.1 Product Development Panel 1

Category	Compliance Requirement	Information	Attestation Da
Pre-Receipt	RFA approved by CPDO	05/04/2018	12/13/2018
	RFA published in Texas.gov eGrants	05/17/2018	12/13/2018
	CPRIT Application Receipt System (CARS) opened	06/28/2018	12/13/2018
	CPRIT Application Receipt System (CARS) closed	08/08/2018	12/13/2018
	Sole application submitted	08/08/2018	12/13/2018
	Method of submission	CARS	12/13/2018
	Within receipt period	YES	12/13/2018
	Request for extension to submit application after CARS closed	NA	12/13/2018
	Request for extension for late application submission accepted	NA	12/13/2018
	Submission of application fee	YES	01/31/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	12/13/2018
	Donation(s) made to CPRIT / Foundation	NO	12/13/2018
	Assigned to primary reviewers	08/30/2018	12/13/2018
	Applicant notified of review panel assignment	08/30/2018	12/12/2018
	Primary Reviewer 1 COI signed	08/22/2018	12/13/2018
	Primary (Advocate) Reviewer 2 COI signed	08/22/2018	12/13/2018
	Primary Reviewer 3 COI signed	08/23/2018	12/13/2018
	Primary Reviewer 4 COI signed	08/24/2018	12/13/2018
Screening Teleconference Meeting	Primary Reviewer 1 critique submitted	09/14/2018	12/13/2018
	Primary (Advocate) Reviewer 2 critique submitted	09/15/2018	12/13/2018
	Primary Reviewer 3 critique submitted	09/18/2018	12/13/2018
	Primary Reviewer 4 critique submitted	09/18/2018	12/13/2018
	COI indicated by non-primary reviewer	Lee Greenberger, Grant Williams	12/13/2018
	COI recused from participation	YES	12/13/2018
	Screening Teleconference Meeting	09/24/2018	12/12/2018
	Post-Screening Teleconference score report	09/24/2018	12/12/2018
	Post review statements signed	10/27/2018	12/12/2018
	Third Party Observer Report	09/26/2018	12/13/2018
	Recommended for On-Site Meeting	YES	12/13/2018
Peer Review Meeting	COI indicated by non-primary reviewer	Lee Greenberger, Grant Williams	12/13/2018
	COI recused from participation	YES	12/13/2018
	Peer Review Meeting	10/23/2018	12/13/2018
	Post Review Meeting End Date	10/24/2018	12/13/2018
	Post review statements signed	10/30/2018	12/13/2018
	Third Party Observer Report	10/30/2018	12/13/2018
	Score report delivered to CPDO	11/05/2018	12/13/2018
	Recommended for due diligence and IP review	YES	12/13/2018
Due Diligence and IP Review	Final due diligence review submitted to PDRC	01/02/2019	01/29/2019
	Intellectual Property conflict check	11/21/2018	01/24/2019
	Final intellectual property review submitted	01/02/2019	01/28/2019
Final PDRC Recommendation	COI indicated by PDRC member	NONE	01/22/2019
	COI recused from participation	NA	01/22/2019
	Due Diligence Evaluation Meeting / PDRC Meeting	01/11/2019	01/22/2019
	Third Party Observer Report	01/17/2019	01/22/2019
	Recommended for grant award	YES	01/22/2019
	PDRC Chair Notification to PIC and OC	01/23/2019	01/29/2019
	COI indicated by PDRC member (Ranking Meeting)	NONE	01/22/2019
	COI recused from participation (Ranking Meeting)	NA	01/22/2019
	PDRC Ranking Meeting	01/22/2019	01/22/2019
	Third Party Observer Report	01/23/2019	01/31/2019
	Recommended for grant award	YES	01/22/2019
PIC Review	COI indicated by PIC member	NONE	01/31/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / Foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP190025
Seed Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Seed Awards for Product Development Research* Request for Applications (RFA). CPRIT received 27 applications in response to this RFA, including two applications that were withdrawn. This application was assigned to the product development panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

Due diligence review meetings spanned a three-day period—January 11, 14, and 22. The extended time period was due to the increased volume of applications that were recommended for due diligence. Additionally, in the PDRC recommendation letter sent to the PIC, three applications recommended by the PDRC were ranked ahead of an application with either an equal to or more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

CPRIT's newly hired Chief Product Development Officer, Cindy WalkerPeach, listened in on the meetings on January 11th and 14th. Prior to due diligence, she certified that she had no conflict of interest, as defined by CPRIT's statute and rules, with the applications that were discussed during due diligence review.

Pursuant to TAC § 702.19(e), I granted the Interim Chief Product Development Officer (CPDO) a waiver from the general prohibition on communication upon a finding that the waiver was in the best interest of the Institute and was not intended to give one applicant advantage over another. The Oversight Committee was notified of the waiver on February 8, 2019, in writing. The waiver allows the Interim CPDO to discuss equity issues with one of the companies.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:53 PM

FY:	2019		
CYCLE:	I		
PROGRAM:	Product Development		
MECHANISM:	Seed Awards for Product Development Research		
APPLICATION ID:	RP190935		
APPLICATION TITLE	Preclinical Development of a Novel T-All Therapeutic Antibody		
APPLICANT NAME:	Kalantharkatty, Abid		
ORGANIZATION:	Alligator Bioscience L LLC		
PANEL NAME:	TS3 Product Development Panel 3		
Category	Compliance Requirement	Performance	Attestation Date
Pre-Receipt	RFA approved by CPDO	05/04/2018	12/11/2018
	RFA published in Texas.gov eGrants	05/17/2018	12/11/2018
	CPRIT Application Receipt System (CARS) opened	06/28/2018	12/11/2018
	CPRIT Application Receipt System (CARS) closed	08/08/2018	12/11/2018
	Date application submitted	08/08/2018	12/11/2018
	Method of submission	CARS	12/11/2018
	Within receipt period	YES	12/11/2018
	Request for extension to submit application after CARS closed	NA	12/13/2018
	Request for extension for late application submission accepted	NA	12/13/2018
	Submission of application fee	YES	01/31/2019
Receipt, Referral, and Assignment	Administrative review notification	08/24/2018	12/13/2018
	Donation(s) made to CPRIT / foundation	NO	12/13/2018
	Assigned to primary reviewers	08/30/2018	12/13/2018
	Applicant notified of review panel assignment	08/30/2018	12/12/2018
	Primary Reviewer 1 COI signed	08/22/2018	12/13/2018
	Primary (Advocate) Reviewer 2 COI signed	08/23/2018	12/13/2018
	Primary Reviewer 3 COI signed	08/22/2018	12/13/2018
	Primary Reviewer 4 COI signed	08/24/2018	12/13/2018
Screening Teleconference Meeting	Primary Reviewer 1 critique submitted	09/09/2018	12/13/2018
	Primary (Advocate) Reviewer 2 critique submitted	09/13/2018	12/13/2018
	Primary Reviewer 3 critique submitted	09/12/2018	12/13/2018
	Primary Reviewer 4 critique submitted	09/14/2018	12/13/2018
	COI indicated by non-primary reviewer	NONE	12/13/2018
	COI recused from participation	NA	12/13/2018
	Screening Teleconference Meeting	09/24/2018	12/12/2018
	Post-Screening Teleconference score report	09/24/2018	12/12/2018
	Post review statements signed	10/27/2018	12/11/2018
	Third Party Observer Report	09/26/2018	12/12/2018
	Recommended for On-Site Meeting	YES	12/13/2018
Peer Review Meeting	COI indicated by non-primary reviewer	NONE	12/13/2018
	COI recused from participation	NA	12/13/2018
	Peer Review Meeting	10/23/2018	12/13/2018
	Peer Review Meeting End Date	10/24/2018	12/13/2018
	Post review statements signed	10/30/2018	12/13/2018
	Third Party Observer Report	10/30/2018	12/13/2018
	Score report delivered to CPDO	11/05/2018	12/13/2018
	Recommended for due diligence and IP review	YES	12/13/2018
Due Diligence and IP Review	Final due diligence review submitted to PDRC	01/02/2019	01/29/2019
	Intellectual Property conflict check	11/21/2018	01/29/2019
	Final intellectual property review submitted	01/02/2019	01/29/2019
Final PDRC Recommendation	COI indicated by PDRC member	NONE	01/22/2019
	COI recused from participation	NA	01/22/2019
	Due Diligence Evaluation Meeting / PDRC Meeting	01/14/2019	01/31/2019
	Third Party Observer Report	01/17/2019	01/22/2019
	Recommended for grant award	YES	01/22/2019
	PDRC Chair Notification to PIC and OC	01/23/2019	01/29/2019
	COI indicated by PDRC member (Ranking Meeting)	NONE	01/22/2019
	COI recused from participation (Ranking Meeting)	NA	01/22/2019
	PDRC Ranking Meeting	01/22/2019	01/22/2019
	Third Party Observer Report	01/23/2019	01/31/2019
	Recommended for grant award	YES	01/22/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP190027
Company Relocation Product Development Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Company Relocation Product Development Awards* Request for Applications (RFA). CPRIT received nine applications in response to this RFA, including one application that was withdrawn. This application was assigned to the product development panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

Due diligence review meetings spanned a three-day period—January 11, 14, and 22. The extended time period was due to the increased volume of applications that were recommended for due diligence. The PDRC took no action on two applications from this mechanism and declined to recommend an application from cycle 18.2. Additionally, in the PDRC recommendation letter sent to the PIC, three applications recommended by the PDRC were ranked ahead of an application with either an equal to or more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

CPRIT's newly hired Chief Product Development Officer, Cindy WalkerPeach, listened in on the meetings on January 11th and 14th. Prior to due diligence, she certified that she had no conflict of interest, as defined by CPRIT's statute and rules, with the applications that were discussed during due diligence review.

Pursuant to TAC § 702.19(e), I granted the Interim Chief Product Development Officer (CPDO) a waiver from the general prohibition on communication upon a finding that the waiver was in the best interest of the Institute and was not intended to give one applicant advantage over another. The Oversight Committee was notified of the waiver on February 8, 2019, in writing. The waiver allows the Interim CPDO to discuss equity issues with one of the companies.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:53 PM

FY:	2019
CYCLE:	1
PROGRAM:	Product Development
MECHANISM:	Company Relocation Product Development Research Awards
APPLICATION ID:	RP190013
APPLICATION TITLE:	A first-in-class anti-VISTA monoclonal antibody for the treatment of MDSC-mediated suppressive
APPLICANT NAME:	Ingram, Piers
ORGANIZATION:	Harmonicyte Discovery Pte Ltd
PANEL NAME:	TX I Product Development Panel 2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA approved by CEDO	05/09/2018	12/12/2018
	RFA published in Texas.gov eGrants	06/17/2018	12/12/2018
	CPRIT Application Receipt System (CARS) opened	06/28/2018	12/13/2018
	CPRIT Application Receipt System (CARS) closed	08/02/2018	12/13/2018
	Date application submitted	08/07/2018	12/14/2018
	Method of submission	CARS	12/14/2018
	Within receipt period	YES	12/14/2018
	Request for extension to submit application after CARS closed	NA	12/14/2018
	Request for extension for late application submission accepted	NA	12/14/2018
	Submission of application fee	YES	01/31/2019
Receipt, Referral, and Assignment	Administrative review notification	08/24/2018	12/14/2018
	Donation(s) made to CPRIT / Foundation	NO	12/14/2018
	Assigned to primary reviewers	08/30/2018	12/14/2018
	Applicant notified of review panel assignment	08/30/2018	12/18/2018
	Primary Reviewer 1 COI signed	08/24/2018	12/14/2018
	Primary (Advocate) Reviewer 2 COI signed	08/22/2018	12/14/2018
	Primary Reviewer 3 COI signed	08/24/2018	12/14/2018
	Primary Reviewer 4 COI signed	08/24/2018	12/14/2018
Screening Teleconference Meeting	Primary Reviewer 1 critique submitted	09/14/2018	12/14/2018
	Primary (Advocate) Reviewer 2 critique submitted	09/20/2018	12/14/2018
	Primary Reviewer 3 critique submitted	09/14/2018	12/14/2018
	Primary Reviewer 4 critique submitted	09/14/2018	12/14/2018
	COI indicated by non-primary reviewer	Vivien Lee	12/14/2018
	COI recused from participation	YES	12/14/2018
	Screening Teleconference Meeting	09/25/2018	12/18/2018
	Post-Screening Teleconference score report	09/25/2018	12/18/2018
	Post review statements signed	11/01/2018	12/18/2018
	Third Party Observer Report	09/27/2018	12/18/2018
	Recommended for On-Site Meeting	YES	12/14/2018
Peer Review Meeting	COI indicated by non-primary reviewer	Vivian Lee	12/18/2018
	COI recused from participation	YES	12/14/2018
	Peer Review Meeting	10/21/2018	12/14/2018
	Peer Review Meeting End Date	10/24/2018	12/14/2018
	Post review statements signed	11/05/2018	12/14/2018
	Third Party Observer Report	10/30/2018	12/14/2018
	Score report delivered to CPDO	11/05/2018	12/14/2018
	Recommended for due diligence and IP review	YES	12/14/2018
Due Diligence and IP Review	Final due diligence review submitted to PDRC	01/02/2019	01/29/2019
	Intellectual Property conflict check	11/15/2018	01/29/2019
	Final intellectual property review submitted	01/02/2019	01/29/2019
Final PDRC Recommendation	COI indicated by PDRC member	NONE	01/22/2019
	COI recused from participation	NA	01/22/2019
	Due Diligence Evaluation Meeting / PDRC Meeting	01/11/2019	01/11/2019
	Third Party Observer Report	01/17/2019	01/17/2019
	Recommended for grant award	YES	01/22/2019
	PDRC Chair Notification to PIC and OC	01/23/2019	01/29/2019
	COI indicated by PDRC member (Ranking Meeting)	NONE	01/22/2019
	COI recused from participation (Ranking Meeting)	NA	01/22/2019
	PDRC Ranking Meeting	01/22/2019	01/22/2019
	Third Party Observer Report	01/23/2019	01/31/2019
	Recommended for grant award	YES	01/22/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI recused from participation	NA	
	Donation(s) made to CPRIT / Foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP190004
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* Request for Applications (RFA). CPRIT received seven applications in response to this RFA. This application was assigned to the prevention panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

At their meeting on January 11, 2019, the Prevention Review Council (PRC) recommended four applications from this mechanism. All four of these applications were recommended ahead of an application with either the same or more favorable score. Additionally, in the PRC recommendation letter, which aggregates and ranks applications that are recommended to the PIC, some applications are ranked ahead of applications with a more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC.

During the peer review panel discussion of an application in this mechanism, Dr. Ross Brownson, a PRC member, declared a conflict of interest and recused himself. When the PRC ranked this application at their review council meeting, Dr. Brownson inadvertently failed to initially disclose the conflict of interest and participated in the discussion, but not the ranking, of the application. Dr. Brownson's participation is addressed by the FY2019 conflict of interest waiver adopted by the Oversight Committee in August 2018 that allows review council members with certain conflicts of interest to participate in discussion of applications that reach the review council stage of application review. I am comfortable that the conflict of interest by the PRC member falls within the allowable limits of this waiver and did not interfere with the integrity of the review process.

I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019
CYCLE:	3
PROGRAM:	Prevention
MECHANISM:	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
APPLICATION ID:	PP190004
APPLICATION TITLE:	Partnering with schools and clinics to expand a highly successful HPV vaccination program for 9-1
APPLICANT NAME:	Berenson, Abbey B
ORGANIZATION:	The University of Texas Medical Branch at Galveston
PANEL NAME:	19.1 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CPO	05/07/2018	01/08/2019
	RFA published in Texas.gov eGrants	07/25/2018	01/08/2019
	CPRIT Application Receipt System (CARS) opened	06/07/2018	01/08/2019
	CPRIT Application Receipt System (CARS) closed	09/05/2018	01/08/2019
	Date application submitted	08/28/2018	01/08/2019
	Method of submission	CARS	01/08/2019
	Within receipt period	YES	01/08/2019
	Request for extension to submit application after CARS closed	NA	01/08/2019
	Request for extension for late application submission accepted	NA	01/08/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/08/2019
	Donation(s) made to CPRIT / foundation	NO	01/08/2019
	Assigned to primary reviewers	10/05/2018	01/08/2019
	Applicant notified of review panel assignment	10/05/2018	01/08/2019
	Primary Reviewer 1 COI signed	10/01/2018	01/08/2019
	Primary (Advocate) Reviewer 2 COI signed	10/02/2018	01/08/2019
	Primary Reviewer 3 COI signed	10/01/2018	01/08/2019
	Primary Reviewer 4 COI signed	09/27/2018	01/08/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	11/26/2018	01/08/2019
	Primary (Advocate) Reviewer 2 critique submitted	10/31/2018	01/08/2019
	Primary Reviewer 3 critique submitted	11/27/2018	01/08/2019
	Primary Reviewer 4 critique submitted	11/20/2018	01/08/2019
	COI indicated by non-primary reviewer	NONE	01/08/2019
	COI recused from participation	NA	01/08/2019
	Discussed at Peer Review Meeting	YES	01/08/2019
	Peer Review Meeting	12/11/2018	01/08/2019
	Peer Review Meeting End Date	12/12/2018	01/08/2019
	Post review statements signed	12/18/2018	01/08/2019
	Third Party Observer Report	12/14/2018	01/08/2019
	Score report delivered to CPO	12/20/2018	01/08/2019
	Recommended for PRC review	YES	01/08/2019
Final PRC Recommendation	COI indicated by PRC member	NONE	01/18/2019
	COI recused from participation	NA	01/18/2019
	PRC Meeting	01/11/2019	01/18/2019
	Third Party Observer Report	01/17/2019	01/31/2019
	Recommended for grant award	YES	01/18/2019
	PRC Chair Notification to PIC and OC	01/14/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment.	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application PP190009
Tobacco Control and Lung Cancer Screening

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Tobacco Control and Lung Cancer Screening* Request for Applications (RFA). CPRIT received four applications in response to this RFA, including one application that was withdrawn. This application was assigned to the prevention panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In the Prevention Review Council (PRC) recommendation letter, which aggregates and ranks applications that are recommended to the PIC, some applications are ranked ahead of applications with a more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019
CYCLE:	1
PROGRAM:	Prevention
MECHANISM:	Tobacco Control and Lung Cancer Screening
APPLICATION ID:	PP190009
APPLICATION TITLE	Expanding Tobacco Use Cessation in Northeast Texas
APPLICANT NAME:	Prokhorov, Alexander V
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center
PANEL NAME:	19.1 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CPO	05/07/2018	01/08/2019
	RFA published in Texas.gov eGrants	05/10/2018	01/08/2019
	CPRIT Application Receipt System (CARS) opened	06/07/2018	01/08/2019
	CPRIT Application Receipt System (CARS) closed	09/05/2018	01/08/2019
	Date application submitted	09/05/2018	01/08/2019
	Method of submission	CARS	01/08/2019
	Within receipt period	YES	01/08/2019
	Request for extension to submit application after CARS closed	NA	01/08/2019
	Request for extension for late application submission accepted	NA	01/08/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/08/2019
	Donation(s) made to CPRIT / foundation	NO	01/08/2019
	Assigned to primary reviewers	10/05/2018	01/08/2019
	Applicant notified of review panel assignment	10/05/2018	01/08/2019
	Primary Reviewer 1 COI signed	09/28/2018	01/08/2019
	Primary (Advocate) Reviewer 2 COI signed	10/02/2018	01/08/2019
	Primary Reviewer 3 COI signed	09/29/2018	01/08/2019
	Primary Reviewer 4 COI signed	10/02/2018	01/08/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	10/29/2018	01/08/2019
	Primary (Advocate) Reviewer 2 critique submitted	10/30/2018	01/08/2019
	Primary Reviewer 3 critique submitted	11/19/2018	01/08/2019
	Primary Reviewer 4 critique submitted	11/28/2018	01/08/2019
	COI indicated by non-primary reviewer	NONE	01/08/2019
	COI recused from participation	NA	01/08/2019
	Discussed at Peer Review Meeting	YES	01/08/2019
	Peer Review Meeting	12/11/2018	01/08/2019
	Post review statements signed	12/18/2018	01/08/2019
	Third Party Observer Report	12/14/2018	01/08/2019
	Score report delivered to CPO	12/20/2018	01/08/2019
	Recommended for PRC review	YES	01/08/2019
Final PRC Recommendation	COI indicated by PRC member	NONE	01/18/2019
	COI recused from participation	NA	01/18/2019
	PRC Meeting	01/11/2019	01/18/2019
	Third Party Observer Report	01/17/2019	01/31/2019
	Recommended for grant award	YES	01/18/2019
	PRC Chair Notification to PIC and OC	01/14/2019	01/31/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP190014
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* Request for Applications (RFA). CPRIT received seven applications in response to this RFA. This application was assigned to the prevention panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

At their meeting on January 11, 2019, the Prevention Review Council (PRC) recommended four applications from this mechanism. All four of these applications were recommended ahead of an application with either the same or more favorable score. Additionally, in the PRC recommendation letter, which aggregates and ranks applications that are recommended to the PIC, some applications are ranked ahead of applications with a more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC.

During the peer review panel discussion of an application in this mechanism, Dr. Ross Brownson, a PRC member, declared a conflict of interest and recused himself. When the PRC ranked this application at their review council meeting, Dr. Brownson inadvertently failed to initially disclose the conflict of interest and participated in the discussion, but not the ranking, of the application. Dr. Brownson's participation is addressed by the FY2019 conflict of interest waiver adopted by the Oversight Committee in August 2018 that allows review council members with certain conflicts of interest to participate in discussion of applications that reach the review council stage of application review. I am comfortable that the conflict of interest by the PRC member falls within the allowable limits of this waiver and did not interfere with the integrity of the review process.

I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019
CYCLE:	1
PROGRAM:	Prevention
MECHANISM:	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
APPLICATION ID:	PP190014
APPLICATION TITLE	Expansion of cervical cancer prevention services to medically underserved populations through patient outre
APPLICANT NAME:	Schmeler, Kathleen M
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center
PANEL NAME:	19.1 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CPO	05/07/2018	01/08/2019
	RFA published in Texas.gov eGrants	07/25/2018	01/08/2019
	CPRIT Application Receipt System (CARS) opened	06/07/2018	01/08/2019
	CPRIT Application Receipt System (CARS) closed	09/05/2018	01/08/2019
	Date application submitted	09/05/2018	01/08/2019
	Method of submission	CARS	01/08/2019
	Within receipt period	YES	01/08/2019
	Request for extension to submit application after CARS closed	NA	01/08/2019
	Request for extension for late application submission accepted	NA	01/08/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/08/2019
	Donation(s) made to CPRIT / foundation	NO	01/08/2019
	Assigned to primary reviewers	10/05/2018	01/08/2019
	Applicant notified of review panel assignment	10/05/2018	01/08/2019
	Primary Reviewer 1 COI signed	09/30/2018	01/08/2019
	Primary (Advocate) Reviewer 2 COI signed	10/02/2018	01/08/2019
	Primary Reviewer 3 COI signed	09/27/2018	01/08/2019
	Primary Reviewer 4 COI signed	09/30/2018	01/08/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	11/26/2018	01/08/2019
	Primary (Advocate) Reviewer 2 critique submitted	11/11/2018	01/08/2019
	Primary Reviewer 3 critique submitted	12/03/2018	01/08/2019
	Primary Reviewer 4 critique submitted	11/26/2018	01/08/2019
	COI indicated by non-primary reviewer	Heather Brandt, Ross Brownson	01/08/2019
	COI recused from participation	YES	01/08/2019
	Discussed at Peer Review Meeting	YES	01/08/2019
	Peer Review Meeting	12/11/2018	01/08/2019
	Peer Review Meeting End Date	12/12/2018	01/08/2019
	Post review statements signed	12/18/2018	01/08/2019
	Third Party Observer Report	12/14/2018	01/08/2019
	Score report delivered to CPO	12/20/2018	01/08/2019
	Recommended for PRC review	YES	01/08/2019
Final PRC Recommendation	COI indicated by PRC member	Ross Brownson	01/18/2019
	COI recused from participation	NO	01/18/2019
	PRC Meeting	01/11/2019	01/18/2019
	Third Party Observer Report	01/17/2019	01/31/2019
	Recommended for grant award	YES	01/18/2019
	PRC Chair Notification to PIC and OC	01/14/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP190021
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* Request for Applications (RFA). CPRIT received seven applications in response to this RFA. This application was assigned to the prevention panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

At their meeting on January 11, 2019, the Prevention Review Council (PRC) recommended four applications from this mechanism. All four of these applications were recommended ahead of an application with either the same or more favorable score. Additionally, in the PRC recommendation letter, which aggregates and ranks applications that are recommended to the PIC, some applications are ranked ahead of applications with a more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC.

During the peer review panel discussion of an application in this mechanism, Dr. Ross Brownson, a PRC member, declared a conflict of interest and recused himself. When the PRC ranked this application at their review council meeting, Dr. Brownson inadvertently failed to initially disclose the conflict of interest and participated in the discussion, but not the ranking, of the application. Dr. Brownson's participation is addressed by the FY2019 conflict of interest waiver adopted by the Oversight Committee in August 2018 that allows review council members with certain conflicts of interest to participate in discussion of applications that reach the review council stage of application review. I am comfortable that the conflict of interest by the PRC member falls within the allowable limits of this waiver and did not interfere with the integrity of the review process.

I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019		
CYCLE:	1		
PROGRAM:	Prevention		
MECHANISM:	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populatio		
APPLICATION ID:	PP190023		
APPLICATION TITLE	Access to Breast and Cervical Care for west Texas (ABC2WT)		
APPLICANT NAME:	Layeequr Rahman, Rakhshanda		
ORGANIZATION:	Texas Tech University Health Sciences Center		
PANEL NAME:	19.1 Prevention Panel-1		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CPO	05/07/2018	01/08/2019
	RFA published in Texas.gov eGrants	07/25/2018	01/08/2019
	CPRIT Application Receipt System (CARS) opened	08/07/2018	01/08/2019
	CPRIT Application Receipt System (CARS) closed	09/05/2018	01/08/2019
	Date application submitted	09/04/2018	01/08/2019
	Method of submission	CARS	01/08/2019
	Within receipt period	YES	01/08/2019
	Request for extension to submit application after CARS closed	NA	01/08/2019
	Request for extension for late application submission accepted	NA	01/08/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/08/2019
	Donation(s) made to CPRIT / foundation	NO	01/08/2019
	Assigned to primary reviewers	10/05/2018	01/08/2019
	Applicant notified of review panel assignment	10/05/2018	01/08/2019
	Primary Reviewer 1 COI signed	09/29/2018	01/08/2019
	Primary (Advocate) Reviewer 2 COI signed	10/02/2018	01/08/2019
	Primary Reviewer 3 COI signed	10/01/2018	01/08/2019
	Primary Reviewer 4 COI signed	09/30/2018	01/08/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	11/24/2018	01/08/2019
	Primary (Advocate) Reviewer 2 critique submitted	11/21/2018	01/08/2019
	Primary Reviewer 3 critique submitted	11/26/2018	01/08/2019
	Primary Reviewer 4 critique submitted	11/13/2018	01/08/2019
	COI indicated by non-primary reviewer	NONE	01/08/2019
	COI recused from participation	NA	01/08/2019
	Discussed at Peer Review Meeting	YES	01/08/2019
	Peer Review Meeting	12/11/2018	01/08/2019
	Peer Review Meeting End Date	12/12/2018	01/08/2019
	Post review statements signed	12/18/2018	01/08/2019
	Third Party Observer Report	12/14/2018	01/08/2019
	Score report delivered to CPO	12/20/2018	01/08/2019
	Recommended for PRC review	YES	01/08/2019
Final PRC Recommendation	COI indicated by PRC member	NONE	01/18/2019
	COI recused from participation	NA	01/18/2019
	PRC Meeting	01/11/2019	01/18/2019
	Third Party Observer Report	01/17/2019	01/31/2019
	Recommended for grant award	YES	01/18/2019
	PRC Chair Notification to PIC and OC	01/14/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP190023
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* Request for Applications (RFA). CPRIT received seven applications in response to this RFA. This application was assigned to the prevention panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

At their meeting on January 11, 2019, the Prevention Review Council (PRC) recommended four applications from this mechanism. All four of these applications were recommended ahead of an application with either the same or more favorable score. Additionally, in the PRC recommendation letter, which aggregates and ranks applications that are recommended to the PIC, some applications are ranked ahead of applications with a more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC.

During the peer review panel discussion of an application in this mechanism, Dr. Ross Brownson, a PRC member, declared a conflict of interest and recused himself. When the PRC ranked this application at their review council meeting, Dr. Brownson inadvertently failed to initially disclose the conflict of interest and participated in the discussion, but not the ranking, of the application. Dr. Brownson's participation is addressed by the FY2019 conflict of interest waiver adopted by the Oversight Committee in August 2018 that allows review council members with certain conflicts of interest to participate in discussion of applications that reach the review council stage of application review. I am comfortable that the conflict of interest by the PRC member falls within the allowable limits of this waiver and did not interfere with the integrity of the review process.

I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Clevland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019		
CYCLE:	1		
PROGRAM:	Prevention		
MECHANISM:	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations		
APPLICATION ID:	PP190023		
APPLICATION TITLE	School-based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuati		
APPLICANT NAME:	Rodriguez, Ana M		
ORGANIZATION:	The University of Texas Medical Branch at Galveston		
PANEL NAME:	19.1 Prevention Panel 1		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CPO	05/07/2018	01/08/2019
	RFA published in Texas.gov eGrants	07/25/2018	01/08/2019
	CPRIT Application Receipt System (CARS) opened	08/07/2018	01/08/2019
	CPRIT Application Receipt System (CARS) closed	09/05/2018	01/08/2019
	Date application submitted	09/05/2018	01/08/2019
	Method of submission	CARS	01/08/2019
	Within receipt period	YES	01/08/2019
	Request for extension to submit application after CARS closed	NA	01/08/2019
	Request for extension for late application submission accepted	NA	01/08/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/08/2019
	Donation(s) made to CPRIT / foundation	NO	01/08/2019
	Assigned to primary reviewers	10/05/2018	01/08/2019
	Applicant notified of review panel assignment	10/05/2018	01/08/2019
	Primary Reviewer 1 COI signed	10/01/2018	01/08/2019
	Primary (Advocate) Reviewer 2 COI signed	10/02/2018	01/08/2019
	Primary Reviewer 3 COI signed	09/30/2018	01/08/2019
	Primary Reviewer 4 COI signed	09/27/2018	01/08/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	11/27/2018	01/08/2019
	Primary (Advocate) Reviewer 2 critique submitted	11/11/2018	01/08/2019
	Primary Reviewer 3 critique submitted	11/26/2018	01/08/2019
	Primary Reviewer 4 critique submitted	11/27/2018	01/08/2019
	COI indicated by non-primary reviewer	NONE	01/08/2019
	COI recused from participation	NA	01/08/2019
	Discussed at Peer Review Meeting	YES	01/08/2019
	Peer Review Meeting	12/11/2018	01/08/2019
	Peer Review Meeting End Date	12/12/2018	01/08/2019
	Post review statements signed	12/18/2018	01/08/2019
	Third Party Observer Report	12/14/2018	01/08/2019
	Score report delivered to CPO	12/20/2018	01/08/2019
	Recommended for PRC review	YES	01/08/2019
Final PRC Recommendation	COI indicated by PRC member	NONE	01/18/2019
	COI recused from participation	NA	01/18/2019
	PRC Meeting	01/11/2019	01/18/2019
	Third Party Observer Report	01/17/2019	01/31/2019
	Recommended for grant award	YES	01/18/2019
	PRC Chair notification to PIC and OC	01/14/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP190027
Tobacco Control and Lung Cancer Screening

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Tobacco Control and Lung Cancer Screening* Request for Applications (RFA). CPRIT received four applications in response to this RFA, including one application that was withdrawn. This application was assigned to the prevention panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In the Prevention Review Council (PRC) recommendation letter, which aggregates and ranks applications that are recommended to the PIC, some applications are ranked ahead of applications with a more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019
CYCLE:	1
PROGRAM:	Prevention
MECHANISM:	Tobacco Control and Lung Cancer Screening
APPLICATION ID:	PP190027
APPLICATION TITLE	Engaging Oral Health Providers for Evidence-Based Tobacco Cessation
APPLICANT NAME:	Jones, Daniel L
ORGANIZATION:	Texas A&M University System Health Science Center
PANEL NAME:	19.1 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CPO	05/07/2018	01/08/2019
	RFA published in Texas.gov eGrants	05/10/2018	01/08/2019
	CPRIT Application Receipt System (CARS) opened	06/07/2018	01/08/2019
	CPRIT Application Receipt System (CARS) closed	09/05/2018	01/08/2019
	Date application submitted	09/05/2018	01/08/2019
	Method of submission	CARS	01/08/2019
	Within receipt period	YES	01/08/2019
	Request for extension to submit application after CARS closed	NA	01/08/2019
	Request for extension for late application submission accepted	NA	01/08/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/08/2019
	Donation(s) made to CPRIT / foundation	NO	01/08/2019
	Assigned to primary reviewers	10/05/2018	01/08/2019
	Applicant notified of review panel assignment	10/05/2018	01/08/2019
	Primary Reviewer 1 COI signed	10/02/2018	01/08/2019
	Primary (Advocate) Reviewer 2 COI signed	10/03/2018	01/08/2019
	Primary Reviewer 3 COI signed	09/28/2018	01/08/2019
	Primary Reviewer 4 COI signed	10/19/2018	01/08/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	12/03/2018	01/08/2019
	Primary (Advocate) Reviewer 2 critique submitted	11/25/2018	01/08/2019
	Primary Reviewer 3 critique submitted	10/29/2018	01/08/2019
	Primary Reviewer 4 critique submitted	11/27/2018	01/08/2019
	COI indicated by non-primary reviewer	NONE	01/08/2019
	COI recused from participation	NA	01/08/2019
	Discussed at Peer Review Meeting	YES	01/08/2019
	Peer Review Meeting	12/11/2018	01/08/2019
	Peer Review Meeting End Date	12/12/2018	01/08/2019
	Post review statements signed	12/18/2018	01/08/2019
	Third Party Observer Report	12/14/2018	01/08/2019
	Score report delivered to CPO	12/20/2018	01/08/2019
	Recommended for PRC review	YES	01/08/2019
Final PRC Recommendation	COI indicated by PRC member	NONE	01/18/2019
	COI recused from participation	NA	01/18/2019
	PRC Meeting	01/11/2019	01/18/2019
	Third Party Observer Report	01/17/2019	01/31/2019
	Recommended for grant award	YES	01/18/2019
	PRC Chair Notification to PIC and OC	01/14/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP190041
Dissemination of CPRIT-Funded
Cancer Control Interventions

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Dissemination of CPRIT-Funded Cancer Control Interventions* Request for Applications (RFA). CPRIT received two applications in response to this RFA. This application was assigned to the Prevention Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In the Prevention Review Council (PRC) recommendation letter, which aggregates and ranks applications that are recommended to the PIC, some applications are ranked ahead of applications with a more favorable score. As allowed in 25 T.A.C. § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019		
CYCLE:	1		
PROGRAM:	Prevention		
MECHANISM:	Dissemination of CPRIT-Funded Cancer Control Interventions		
APPLICATION ID:	PP190041		
APPLICATION TITLE	Adolescent Vaccination Program: Online Decision Support for Adoption of Evidence-based HPV		
APPLICANT NAME:	Skegg, Ross		
ORGANIZATION:	The University of Texas Health Science Center at Houston		
PANEL NAME:	19.1 Prevention DI		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CPO	05/07/2018	01/17/2019
	RFA published in Texas.gov eGrants	05/10/2018	01/17/2019
	CPRIT Application Receipt System (CARS) opened	06/07/2018	01/17/2019
	19.1 CARS Application Receipt System (CARS) closed	12/03/2018	01/17/2019
	CPRIT Application Receipt System (CARS) closed	NA	01/17/2019
	Date application submitted	12/03/2018	01/17/2019
	Method of submission	CARS	01/17/2019
	Within receipt period	YES	01/17/2019
	Request for extension to submit application after CARS closed	NA	01/17/2019
	Request for extension for late application submission accepted	NA	01/17/2019
Receipt, Referral, and Assignment	Administrative review notification	12/06/2018	01/17/2019
	Donation(s) made to CPRIT / foundation	NO	01/17/2019
	Assigned to primary reviewers	12/12/2018	01/17/2019
	Applicant notified of review panel assignment	NA	01/17/2019
	Primary Reviewer 1 COI signed	12/07/2018	01/17/2019
	Primary (Advocate) Reviewer 2 COI signed	NA	01/17/2019
	Primary Reviewer 3 COI signed	12/10/2018	01/17/2019
	Primary Reviewer 4 COI signed	12/08/2018	01/17/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	01/06/2019	01/17/2019
	Primary (Advocate) Reviewer 2 critique submitted	NA	01/17/2019
	Primary Reviewer 3 critique submitted	12/28/2018	01/17/2019
	Primary Reviewer 4 critique submitted	NA	01/17/2019
	COI indicated by non-primary reviewer	NONE	01/17/2019
	COI recused from participation	NA	01/17/2019
	Discussed at Peer Review Meeting	YES	01/17/2019
	Peer Review Meeting	01/11/2019	01/17/2019
	Post review statements signed	01/14/2019	01/17/2019
	Third Party Observer Report	01/15/2019	01/17/2019
	Score report delivered to CPO	01/18/2019	01/21/2019
	Recommended for PRC review	YES	01/17/2019
Final PRC Recommendation	COI indicated by PRC member	NONE	01/17/2019
	COI recused from participation	NA	01/17/2019
	PRC Meeting	01/11/2019	01/17/2019
	Third Party Observer Report	01/15/2019	01/17/2019
	Third Party Observer Report-PRC Ranking Meeting	01/17/2019	01/31/2019
	Recommended for grant award	YES	01/17/2019
	PRC Chair Notification to PIC and GC	01/14/2019	01/30/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190002
Individual Investigator Research Awards for
Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 37 applications in response to this RFA, including two applications that were withdrawn. This application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

  The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

  The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer two award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 01/07/2019 10:58 AM

FY:	RR19		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Cancer in Children and Adolescents		
APPLICATION ID:	RP190002		
APPLICATION TITLE	Development of a Precision Drug to Target STAG2 (SA2) Mutant Ewing Sarcoma		
APPLICANT NAME:	Paul Delgrosso		
ORGANIZATION:	Baylor College of Medicine		
PANEL NAME:	Clinical/Translational Cancer Research		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	04/04/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / Foundation	NO	12/26/2018
	Assigned to primary reviewers	08/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/26/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/29/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	06/04/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/19/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/11/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	09/20/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/11/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/17/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/16/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/16/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/03/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/25/2018	12/26/2018
	Post review statements signed	11/12/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / Foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190012
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:58 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190012		
APPLICATION TITLE	Berberine in Prevention of Biochemical Recurrence		
APPLICANT NAME:	Kumar, Addanki P		
ORGANIZATION:	The University of Texas Health Science Center at San Antonio		
PANEL NAME:	Cancer Prevention Research		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/03/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/04/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/20/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/26/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/12/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/03/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/16/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/21/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/07/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/01/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/02/2018	12/26/2018
	Primary Reviewer 2 critique submitted	09/21/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/02/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/15/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/24/2018	12/26/2018
	Post review statements signed	10/31/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/30/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
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	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/30/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190019
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

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The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:58 AM

FY:	2018		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Award		
APPLICATION ID:	RP180015		
APPLICATION TITLE	Lymphatic delivery of checkpoint blockade inhibitors for more effective immunothe		
APPLICANT NAME:	Levick, Eva M.		
ORGANIZATION:	The University of Texas Health Science Center at Houston		
PANEL NAME:	Imaging Technology and Informatics		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/01/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/12/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/12/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/15/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/03/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/21/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	Anna Wu	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/16/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/21/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/05/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/05/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/11/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/10/2018	12/26/2018
	COI indicated by non-primary reviewer	Anna Wu	12/26/2018
	COI recused from participation	YES	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/18/2018	12/26/2018
	Post review statements signed	11/02/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190022
Individual Investigator Research Awards for
Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 36 applications in response to this RFA, including one application that was withdrawn. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:58 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Prevention and Early Detection		
APPLICATION ID:	RP190022		
APPLICATION TITLE:	A randomized, controlled trial comparing the immunogenicity of 2 doses vs 3 doses of the 9-va		
APPLICANT NAME:	Herrmann, Abbey B		
ORGANIZATION:	The University of Texas Medical Branch at Galveston		
PANEL NAME:	Cancer Prevention Research		
Category	Compliance Requirement	Information	Milestone Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	05/31/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	06/07/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/19/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/10/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/19/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/19/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/20/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/03/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/14/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/02/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/16/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/03/2018	12/26/2018
	Primary Reviewer 3 critique submitted	09/24/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/15/2018	12/26/2018
	COI indicated by non primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/24/2018	12/26/2018
	Peer review statements signed	10/31/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190029
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-2 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:58 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190029		
APPLICATION TITLE:	The EZH2 dual-specificity PARP1 as a therapeutic target in breast cancer		
APPLICANT NAME:	Mo, LI		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Basic Cancer Research-2		
Category	Compliance Requirement	Information	Transaction Date
Pre Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	03/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/02/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	05/15/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	06/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/18/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/18/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	06/28/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/04/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/19/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/01/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/22/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/16/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/14/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/22/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/22/2018	12/26/2018
	Post review statements signed	10/25/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/24/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190043
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:58 AM

FY:	2019		
CYCLE:	2		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190083		
APPLICATION TITLE:	Mitochondrial metabolism and RNA methylation in cancer		
APPLICANT NAME:	Aguirre, Ricardo		
ORGANIZATION:	The University of Texas Health Science Center at San Antonio		
PANEL NAME:	Cancer Biology		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published to Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/08/2018	11/01/2018
	Date application submitted	06/04/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	09/06/2018	12/26/2018
	Applicant notified of review panel assignment	07/03/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/14/2018	12/26/2018
	Primary Reviewer 3 COI signed	10/12/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/31/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	NA	12/26/2018
	Primary Reviewer 2 critique submitted	NA	12/26/2018
	Primary Reviewer 3 critique submitted	NA	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NA	12/26/2018
	Preliminary Evaluation score summary sent to Chair	NA	12/26/2018
	Recommended for full review	NA	12/26/2018
	Applicant notified of outcome	NA	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/06/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/14/2018	12/26/2018
	Primary Reviewer 3 COI signed	10/12/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/31/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/14/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/14/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/06/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/22/2018	12/26/2018
	Post review statements signed	10/22/2018	12/26/2018
	Third Party Observer Report	10/10/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190049
Individual Investigator Research Awards for
Clinical Translation

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Clinical Translation* Request for Applications (RFA). CPRIT received 33 applications in response to this RFA, including one application that was withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Clinical Translation		
APPLICATION ID:	RP190249		
APPLICATION TITLE	Non-invasive Detection and Assessment of Therapy Response in Multiple Myeloma using Wh		
APPLICANT NAME:	Madhuranthakam, Ananth J		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Imaging Technology and Informatics		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	01/01/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/05/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	06/07/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/21/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/21/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/15/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/18/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/06/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/16/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/22/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/31/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/07/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/08/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/04/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/27/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/18/2018	12/26/2018
	Post review statements signed	11/02/2018	11/16/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP190067
Individual Investigator Research Awards for
Clinical Translation

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Clinical Translation* Request for Applications (RFA). CPRIT received 33 applications in response to this RFA, including one application that was withdrawn. This application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Clinical Translation		
APPLICATION ID:	RP190097		
APPLICATION TITLE	Improving T cell Therapy of Neuroblastoma with a Novel Cytokine Modulator: A Phase I		
APPLICANT NAME:	Rooney, Cliona M		
ORGANIZATION:	Baylor College of Medicine		
PANEL NAME:	Clinical/Translational Cancer Research		
Category	Compliance Requirement	Information	Association Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/05/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/24/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/13/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/16/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/19/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/08/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/17/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/07/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/10/2018	12/26/2018
	Primary Reviewer 2 critique submitted	09/11/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/24/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/25/2018	12/26/2018
	Post review statements signed	11/12/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190077
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-2 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2018		
CYCLE:	I		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP180077		
APPLICATION TITLE	Molecular Action of Phospho-ERDR Targeting Compounds in Breast Cancer		
APPLICANT NAME:	Chiang, Cheng-Ming		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Basic Cancer Research-3		
Category	Compliance Requirement	Information	Attestation Date
Pre Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	05/29/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / Foundation	NO	12/26/2018
	Assigned to primary reviewers	08/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/18/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/16/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/18/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	09/04/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/14/2018	12/26/2018
	Primary Reviewer 3 critique submitted	09/19/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	Thomas Kodadek	12/26/2018
	Preliminary Evaluation score summary sent to Chair	09/17/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/06/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/07/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/08/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/15/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/12/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/10/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/23/2018	12/26/2018
	COI indicated by non-primary reviewer	Thomas Kodadek	12/26/2018
	COI recused from participation	YES	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/23/2018	12/26/2018
	Post review statements signed	10/25/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / Foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:

Comment — Created Date

Administrative withdrawal reversed following applicant appeal — 2018-11-14 11:30:48

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190107
Individual Investigator Research Awards for
Computational Biology

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Computational Biology* Request for Applications (RFA). CPRIT received 27 applications in response to this RFA, including three applications that were withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer two award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 3rd day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Computational Biology		
APPLICATION ID:	RP190107		
APPLICATION TITLE	Digital pathology analysis for lung cancer patient care		
APPLICANT NAME:	Xiao, Guanghua		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Imaging Technology and Informatics		
Category	Compliance Requirement	Assumption	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/14/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/12/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/13/2018	12/26/2018
	Primary Reviewer 2 critique submitted	NA	12/26/2018
	Primary Reviewer 3 critique submitted	08/07/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/16/2018	12/26/2018
	Primary Reviewer 3 COI signed	09/07/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/08/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/11/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/08/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/27/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/14/2018	12/26/2018
	Peer review statements signed	11/02/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190131
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190533		
APPLICATION TITLE	Nanotheranostic treatment response monitoring of breast cancer with molecular phenotyping		
APPLICANT NAME:	Rosenblum, Richard		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Imaging Technology and Informatics		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/04/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donations(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/20/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/12/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/15/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/05/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/03/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/06/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	08/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/11/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 3 COI signed	10/01/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/04/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/05/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/03/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/10/2018	12/26/2018
	COI indicated by non primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/18/2018	12/26/2018
	Post review statements signed	11/02/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI recused from participation	NA	
	Donations(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190132
Individual Investigator Research Awards for
Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 37 applications in response to this RFA, including two applications that were withdrawn. This application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

  The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

  The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer two award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Cancer in Children and Adolescents		
APPLICATION ID:	RP190132		
APPLICATION TITLE:	Multi-omic Biomarker Discovery for Therapy-related Neurocognitive Impairment in Childhood A		
APPLICANT NAME:	Brown, Austin L		
ORGANIZATION:	Baylor College of Medicine		
PANEL NAME:	Clinical/Translational Cancer Research		
Category	Compliance Requirement	Information	Attestation Date
Pre Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/05/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	06/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/26/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/06/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/12/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/19/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/20/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	09/11/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/01/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/06/2018	12/26/2018
	Primary Reviewer 1 critique submitted	09/30/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/21/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/17/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/12/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/25/2018	12/26/2018
	Post review statements signed	11/12/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	
Comments:			
Comment			Created Date
No Comment			

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP190160
Individual Investigator Research Awards for
Clinical Translation

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Clinical Translation* Request for Applications (RFA). CPRIT received 33 applications in response to this RFA, including one application that was withdrawn. This application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Clinical Translation		
APPLICATION ID:	RP190100		
APPLICATION TITLE:	Interleukin-15 and -21 armored glypican-3 specific CAR T cells for patients with hepatocellu		
APPLICANT NAME:	Hecker, Andrea		
ORGANIZATION:	Baylor College of Medicine		
PANEL NAME:	Clinical/Translational Cancer Research		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/05/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/26/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/25/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/22/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/17/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/17/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/12/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/16/2018	12/26/2018
	Primary Reviewer 2 critique submitted	09/14/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/03/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/25/2018	12/26/2018
	Peer review statements signed	11/17/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CSO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190192
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-1 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	II		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190157		
APPLICATION TITLE	Pharmacological targeting of the IRE1/XBP1 pathway for triple-negative breast cancer		
APPLICANT NAME:	Koong, Albert		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Basic Cancer Research 1		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	11/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/01/2018	12/24/2018
	Method of submission	CARS	12/24/2018
	Within receipt period	YES	12/24/2018
	Request for extension to submit application after CARS closed	NA	12/24/2018
	Request for extension for late application submission accepted	NA	12/24/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/24/2018
	Donation(s) made to CPRIT / foundation	NO	12/24/2018
	Assigned to primary reviewers	08/02/2018	12/24/2018
	Applicant notified of review panel assignment	07/09/2018	12/24/2018
	Primary Reviewer 1 COI signed	06/16/2018	12/24/2018
	Primary Reviewer 2 COI signed	07/26/2018	12/24/2018
	Primary Reviewer 3 COI signed	06/14/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/14/2018	12/24/2018
	Primary Reviewer 2 critique submitted	08/20/2018	12/24/2018
	Primary Reviewer 3 critique submitted	08/14/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/24/2018
	COI indicated by non-primary reviewer	NONE	12/24/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/24/2018
	Recommended for full review	YES	12/24/2018
	Applicant notified of outcome	09/28/2018	12/24/2018
Peer Review Meeting	Assigned to primary reviewers	09/06/2018	12/24/2018
	Primary Reviewer 1 COI signed	08/10/2018	12/24/2018
	Primary Reviewer 2 COI signed	08/20/2018	12/24/2018
	Primary Reviewer 3 COI signed	08/02/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
	Primary Reviewer 1 critique submitted	09/17/2018	12/24/2018
	Primary Reviewer 2 critique submitted	10/09/2018	12/24/2018
	Primary Reviewer 3 critique submitted	09/29/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/03/2018	12/24/2018
	COI indicated by non-primary reviewer	NONE	12/24/2018
	COI recused from participation	NA	12/24/2018
	Discussed at Peer Review Meeting	YES	12/24/2018
	Peer Review Meeting	10/19/2018	12/24/2018
	Post review statements signed	10/22/2018	12/24/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/04/2018	12/24/2018
	Recommended for SRC review	YES	12/24/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/24/2018
	COI recused from participation	NA	12/24/2018
	SRC Meeting	12/05/2018	12/24/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/24/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Promised to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190207
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2018
CYCLE:	1
PROGRAM:	Research
MECHANISM:	Individual Investigator Research Awards
APPLICATION ID:	RP190307
APPLICATION TITLE:	Understanding the role of FBXW7 as a defining driver of uterine carcinosarcoma
APPLICANT NAME:	Castrillon, Diego H
ORGANIZATION:	The University of Texas Southwestern Medical Center
PANEL NAME:	Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/02/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/12/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/13/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/31/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/31/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/07/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/08/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/21/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/23/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/06/2018	12/26/2018
	Primary Reviewer 1 COI signed	09/11/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/01/2018	12/26/2018
	Primary Reviewer 3 COI signed	09/25/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/11/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/10/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/09/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/11/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/06/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/22/2018	12/26/2018
	Post review statements signed	10/22/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190210
Individual Investigator Research Awards for
Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 36 applications in response to this RFA, including one application that was withdrawn. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Prevention and Early Detection		
APPLICATION ID:	RP180030		
APPLICATION TITLE	Improving the Quality of Smoking Cessation and Shared Decision Making for Lung Cancer Screening: A Cluste		
APPLICANT NAME:	Volk, Robert J		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Cancer Prevention Research		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	03/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/14/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/20/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/19/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/19/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	Robert Schnoll, Thomas Brandon	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	10/08/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/01/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/03/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/24/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/13/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/15/2018	12/26/2018
	COI indicated by non-primary reviewer	Thomas Brandon, Robert Schnoll	12/26/2018
	COI recused from participation	YES	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/24/2018	12/26/2018
	Post review statements signed	10/31/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comment(s)	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190211
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019
CYCLE:	1
PROGRAM:	Research
MECHANISM:	Individual Investigator Research Awards
APPLICATION ID:	RP190211
APPLICATION TITLE	Assessments of Tumor Perfusion with Dynamic Contrast Enhanced Multispectral Optoacoustic
APPLICANT NAME:	Pagel, Mark D
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center
PANEL NAME:	Imaging Technology and Informatics

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/01/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	06/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/21/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/12/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/12/2018	12/26/2018
	Primary [Advocate] Reviewer 4 COI signed	08/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 3 critique submitted	NA	12/26/2018
	Primary [Advocate] Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	James Basilion	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/22/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/16/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/31/2018	12/26/2018
	Primary [Advocate] Reviewer 4 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/06/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/09/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/03/2018	12/26/2018
	Primary [Advocate] Reviewer 4 critique submitted	09/10/2018	12/26/2018
	COI indicated by non-primary reviewer	James Basilion	12/26/2018
	COI recused from participation	YES	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/18/2018	12/26/2018
	Post review statements signed	11/02/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190218
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-1 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190218		
APPLICATION TITLE:	Deciphering the underlying biology and translational relevance of PD-L2		
APPLICANT NAME:	Curran, Michael A		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Basic Cancer Research 1		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	05/06/2018	11/01/2018
	Date application submitted	05/30/2018	12/24/2018
	Method of submission	CARS	12/24/2018
	Within receipt period	YES	12/24/2018
	Request for extension to submit application after CARS closed	NA	12/24/2018
	Request for extension for late application submission accepted	NA	12/24/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/24/2018
	Donation(s) made to CPRIT / foundation	NO	12/24/2018
	Assigned to primary reviewers	08/02/2018	12/24/2018
	Applicant notified of review panel assignment	07/09/2018	12/24/2018
	Primary Reviewer 1 COI signed	07/13/2018	12/24/2018
	Primary Reviewer 2 COI signed	06/15/2018	12/24/2018
	Primary Reviewer 3 COI signed	06/12/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/20/2018	12/24/2018
	Primary Reviewer 2 critique submitted	08/31/2018	12/24/2018
	Primary Reviewer 3 critique submitted	08/03/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/24/2018
	COI indicated by non-primary reviewer	NONE	12/24/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/24/2018
	Recommended for full review	YES	12/24/2018
	Applicant notified of outcome	09/28/2018	12/24/2018
Peer Review Meeting	Assigned to primary reviewers	09/06/2018	12/24/2018
	Primary Reviewer 1 COI signed	08/02/2018	12/24/2018
	Primary Reviewer 2 COI signed	10/05/2018	12/24/2018
	Primary Reviewer 3 COI signed	07/31/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
	Primary Reviewer 1 critique submitted	10/12/2018	12/24/2018
	Primary Reviewer 2 critique submitted	10/14/2018	12/24/2018
	Primary Reviewer 3 critique submitted	10/11/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/19/2018	12/24/2018
	COI indicated by non-primary reviewer	NONE	12/24/2018
	COI recused from participation	NA	12/24/2018
	Discussed at Peer Review Meeting	YES	12/24/2018
	Peer Review Meeting	10/19/2018	12/24/2018
	Post review statements signed	10/22/2018	12/24/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/24/2018
	Recommended for SRC review	YES	12/24/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/24/2018
	COI recused from participation	NA	12/24/2018
	SRC Meeting	12/05/2018	12/24/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/24/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190233
Individual Investigator Research Awards for
Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 37 applications in response to this RFA, including two applications that were withdrawn. This application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

  The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

  The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer two award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 28th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 10:59 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Cancer in Children and Adolescents		
APPLICATION ID:	RP190113		
APPLICATION TITLE	Improving Safety and Efficacy of Amino Acid Depletion Therapy for Acute Lymphoblastic Leuk		
APPLICANT NAME:	Lee, Jacques		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Clinical/Translational Cancer Research		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	03/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	03/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	06/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/25/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	06/04/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/13/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/18/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/19/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/08/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/15/2018	12/26/2018
	Primary Reviewer 3 COI signed	09/09/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
	Primary Reviewer 1 critique submitted	09/18/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/18/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/07/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/03/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/25/2018	12/26/2018
	Post review statements signed	11/12/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	
Comments:			
Comment			Created Date
No Comments			

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190235
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-2 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2018		
CYCLE:	I		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190223		
APPLICATION TITLE	Role of Long Non-Coding RNAs in Breast Cancer: Identification, Characterization, and Detecti		
APPLICANT NAME:	Kraus, W. Lee		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Basic Cancer Research 2		
Category	Completed Requirement	Information	Attestation Time
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/05/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / Foundation	NO	12/26/2018
	Assigned to primary reviewers	09/07/2018	12/26/2018
	Applicant notified of review panel assignment	09/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/24/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/12/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	NA	12/26/2018
	Primary Reviewer 2 critique submitted	NA	12/26/2018
	Primary Reviewer 3 critique submitted	NA	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NA	12/26/2018
	Preliminary Evaluation score summary sent to Chair	NA	12/26/2018
	Recommended for full review	NA	12/26/2018
	Applicant notified of outcome	NA	12/26/2018
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	Primary Reviewer 1 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/24/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/12/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/15/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/15/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/15/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/14/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/23/2018	12/26/2018
	Post review statements signed	10/25/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIE and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / Foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190236
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-2 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 28th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190335		
APPLICATION TITLE	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes		
APPLICANT NAME:	Kraus, W. Lee		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Basic Cancer Research 2		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/03/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/05/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	09/07/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/08/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/22/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	NA	12/26/2018
	Primary Reviewer 2 critique submitted	NA	12/26/2018
	Primary Reviewer 3 critique submitted	NA	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NA	12/26/2018
	Preliminary Evaluation score summary sent to Chair	NA	12/26/2018
	Recommended for full review	NA	12/26/2018
	Applicant notified of outcome	NA	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/08/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/16/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/15/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/10/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/23/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/23/2018	12/26/2018
	Post review statements signed	10/25/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190252
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2019
CYCLE:	1
PROGRAM:	Research
MECHANISM:	Individual Investigator Research Awards
APPLICATION ID:	RP190232
APPLICATION TITLE	A novel therapy targeting prostate cancer-induced aberrant bone formations
APPLICANT NAME:	Lin, Sue-Hwa
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center
PANEL NAME:	Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/01/2018	11/03/2018
	RFA published to Texas.gov eGrants	01/19/2018	11/03/2018
	CPRIT Application Receipt System (CARS) opened	03/01/2018	11/03/2018
	CPRIT Application Receipt System (CARS) closed	08/06/2018	11/03/2018
	Date application submitted	08/01/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	08/03/2018	12/26/2018
	Duration(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/02/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/02/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/12/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/12/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	06/11/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/21/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/07/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/19/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/21/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	08/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	08/06/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/31/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/14/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/31/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/31/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/15/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/14/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/11/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/06/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/22/2018	12/26/2018
	Post review statements signed	10/22/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/24/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Duration(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments	Created Date
Reviewed No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190256
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-1 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 13175703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2019
CYCLE:	1
PROGRAM:	Research
MECHANISM:	Individual Investigator Research Awards
APPLICATION ID:	RP190256
APPLICATION TITLE	Role of STIM1 in exercise-induced tumor vascular remodeling
APPLICANT NAME:	Schadler, Keri
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center
PANEL NAME:	Basic Cancer Research-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/15/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/05/2018	12/24/2018
	Method of submission	CARS	12/24/2018
	Within receipt period	YES	12/24/2018
	Request for extension to submit application after CARS closed	NA	12/24/2018
	Request for extension for late application submission accepted	NA	12/24/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/24/2018
	Donation(s) made to CPRIT / foundation	NO	12/24/2018
	Assigned to primary reviewers	06/07/2018	12/24/2018
	Applicant notified of review panel assignment	07/09/2018	12/24/2018
	Primary Reviewer 1 COI signed	06/18/2018	12/24/2018
	Primary Reviewer 2 COI signed	07/16/2018	12/24/2018
	Primary Reviewer 3 COI signed	06/18/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/19/2018	12/24/2018
	Primary Reviewer 2 critique submitted	08/10/2018	12/24/2018
	Primary Reviewer 3 critique submitted	08/14/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/24/2018
	COI indicated by non-primary reviewer	NONE	12/24/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/24/2018
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	Applicant notified of outcome	09/28/2018	12/24/2018
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	Primary Reviewer 1 COI signed	09/10/2018	12/24/2018
	Primary Reviewer 2 COI signed	09/06/2018	12/24/2018
	Primary Reviewer 3 COI signed	08/02/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
	Primary Reviewer 1 critique submitted	10/12/2018	12/24/2018
	Primary Reviewer 2 critique submitted	10/07/2018	12/24/2018
	Primary Reviewer 3 critique submitted	10/05/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/24/2018	12/24/2018
	COI indicated by non-primary reviewer	NONE	12/24/2018
	COI recused from participation	NA	12/24/2018
	Discussed at Peer Review Meeting	YES	12/24/2018
	Peer Review Meeting	10/19/2018	12/24/2018
	Post review statements signed	10/22/2018	12/24/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/24/2018
	Recommended for SRC review	YES	12/24/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/24/2018
	COI recused from participation	NA	12/24/2018
	SRC Meeting	12/05/2018	12/24/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/24/2018
	SRC Chair Notification to PIC and OC	01/14/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP190278
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2019		
CYCLE:	II		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190278		
APPLICATION TITLE	Investigating brain tumor drug delivery by optical modulation of blood-brain barrier using pla		
APPLICANT NAME:	Qin, Zhenpeng		
ORGANIZATION:	The University of Texas at Dallas		
PANEL NAME:	Imaging Technology and Informatics		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	07/05/2018	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/13/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/14/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/17/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/21/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/03/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	09/05/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/01/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/02/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/14/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/09/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/01/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/10/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/18/2018	12/26/2018
	Post review statements signed	11/02/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190279
Individual Investigator Research Awards for
Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 36 applications in response to this RFA, including one application that was withdrawn. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Prevention and Early Detection		
APPLICATION ID:	RP170175		
APPLICATION TITLE	Mechanisms of Prevention of Polycyclic Aromatic Hydrocarbon (PAH)-mediated Lung Carcinogenesis		
APPLICANT NAME:	Moorthy, Bhagavatula		
ORGANIZATION:	Baylor College of Medicine		
PANEL NAME:	Cancer Prevention Research		
Category	Compliance Requirement	Information	Attestation Date
Pre Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/07/2018
	Method of submission	CAPS	12/07/2018
	Within receipt period	YES	12/07/2018
	Request for extension to submit application after CARS closed	NA	12/07/2018
	Request for extension for late application submission accepted	NA	12/07/2018
Receipt, Referral, and Assignment	Administrative review notification	07/05/2018	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/01/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/20/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/15/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/20/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/16/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/11/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/20/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	08/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/07/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/01/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/02/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/16/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/13/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/11/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/24/2018	12/26/2018
	Post review statements signed	10/31/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
Administrative withdrawal reversed following applicant appeal.	2018-11-14 15:06:14.823

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190295
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-2 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190295		
APPLICATION TITLE	Targeting hypoxia/fatty acid uptake in myelodysplastic syndromes		
APPLICANT NAME:	Colla, Simona		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Basic Cancer Research-2		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/09/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/01/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/23/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/18/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/19/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/19/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	01/07/2019
	Primary Reviewer 1 COI signed	09/24/2018	01/07/2019
	Primary Reviewer 2 COI signed	08/01/2018	01/07/2019
	Primary Reviewer 3 COI signed	06/22/2018	01/07/2019
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	01/07/2019
	Primary Reviewer 1 critique submitted	10/16/2018	01/07/2019
	Primary Reviewer 2 critique submitted	12/27/2018	01/07/2019
	Primary Reviewer 3 critique submitted	10/14/2018	01/07/2019
	Primary (Advocate) Reviewer 4 critique submitted	10/23/2018	01/07/2019
	COI indicated by non-primary reviewer	NONE	01/07/2019
	COI recused from participation	NA	01/07/2019
	Discussed at Peer Review Meeting	YES	01/07/2019
	Peer Review Meeting	10/23/2018	01/07/2019
	Post review statements signed	10/23/2018	01/07/2019
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	01/07/2019
	Recommended for SRC review	YES	01/07/2019
Final SRC Recommendation	COI indicated by SRC member	NA	01/07/2019
	COI recused from participation	NA	01/07/2019
	SRC Meeting	12/05/2018	01/07/2019
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	01/07/2019
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP190301
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-1 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2019		
CYCLE:	3		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190301		
APPLICATION TITLE	Biophysical mechanisms of human microbiome-mediated wound healing		
APPLICANT NAME:	Finkelstein, Ilya J		
ORGANIZATION:	The University of Texas at Austin		
PANEL NAME:	Basic Cancer Research-1		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/24/2018
	Method of submission	CARS	12/24/2018
	Within receipt period	YES	12/24/2018
	Request for extension to submit application after CARS closed	NA	12/24/2018
	Request for extension for late application submission accepted	NA	12/24/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/24/2018
	Donation(s) made to CPRIT / foundation	NO	12/24/2018
	Assigned to primary reviewers	08/08/2018	12/24/2018
	Applicant notified of review panel assignment	07/09/2018	12/24/2018
	Primary Reviewer 1 COI signed	07/16/2018	12/24/2018
	Primary Reviewer 2 COI signed	06/13/2018	12/24/2018
	Primary Reviewer 3 COI signed	06/19/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/16/2018	12/24/2018
	Primary Reviewer 2 critique submitted	08/19/2018	12/24/2018
	Primary Reviewer 3 critique submitted	08/14/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/24/2018
	COI indicated by non-primary reviewer	Carol Prives, Walter Chazin, Alan Tomkinson	12/24/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/24/2018
	Recommended for full review	YES	12/24/2018
	Applicant notified of outcome	09/28/2018	12/24/2018
Peer Review Meeting	Assigned to primary reviewers	09/25/2018	12/24/2018
	Primary Reviewer 1 COI signed	08/10/2018	12/24/2018
	Primary Reviewer 2 COI signed	07/31/2018	12/24/2018
	Primary Reviewer 3 COI signed	10/05/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
	Primary Reviewer 1 critique submitted	10/07/2018	12/24/2018
	Primary Reviewer 2 critique submitted	10/11/2018	12/24/2018
	Primary Reviewer 3 critique submitted	10/15/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/03/2018	12/24/2018
	COI indicated by non-primary reviewer	James Manley	12/24/2018
	COI recused from participation	YES	12/24/2018
	Discussed at Peer Review Meeting	YES	12/24/2018
	Peer Review Meeting	10/19/2018	12/24/2018
	Post review statements signed	10/22/2018	12/24/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/24/2018
	Recommended for SRC review	YES	12/24/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/24/2018
	COI recused from participation	NA	12/24/2018
	SRC Meeting	12/01/2018	12/24/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/24/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190326
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:00 AM

FY:	2018		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP180326		
APPLICATION TITLE:	Therapeutic Potential of T Follicular Helper Cells for Melanoma Treatment		
APPLICANT NAME:	Nurieva, Reza		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Clinical/Translational Cancer Research		
Category	Compliance Requirement	Information	Attestation Date
Pre Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/04/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / Foundation	NO	12/26/2018
	Assigned to primary reviewers	08/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/26/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/16/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/09/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/10/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	Steven Dubinett, Victor Engelhard	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/28/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 3 COI signed	10/13/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	09/04/2018	12/26/2018
	Primary Reviewer 1 critique submitted	09/28/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/11/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/01/2018	12/26/2018
	COI indicated by non-primary reviewer	Steven Dubinett, Victor Engelhard	12/26/2018
	COI recused from participation	YES	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/25/2018	12/26/2018
	Post review statements signed	11/12/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/29/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/14/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190360
Individual Investigator Research Awards for
Clinical Translation

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Clinical Translation* Request for Applications (RFA). CPRIT received 33 applications in response to this RFA, including one application that was withdrawn. This application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:01 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Clinical Translation		
APPLICATION ID:	RP190345		
APPLICATION TITLE	Immunotherapeutic Targeting of STAT3/A2 for Treatment of Oral Melanoma		
APPLICANT NAME:	Yan, Carolyn		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Clinical/Translational Cancer Research		
Category	Compliance Requirement	Submission	Attestation Date
Pre-Receipt	RFA Approved by CSO	03/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	03/15/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/01/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/06/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/25/2018	12/26/2018
	Primary Reviewer 2 COI signed	06/27/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/26/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	06/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/13/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/18/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/08/2018	12/26/2018
	Primary Reviewer 2 COI signed	10/04/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/01/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/07/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/07/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/17/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/24/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/25/2018	12/26/2018
	Post review statements signed	11/12/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP190385
Individual Investigator Research Awards for
Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 37 applications in response to this RFA, including two applications that were withdrawn. This application was assigned to the Basic Cancer Research-1 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer two award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:01 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Cancer in Children and Adolescents		
APPLICATION ID:	RP190385		
APPLICATION TITLE:	Growth Signaling in Ewing Sarcoma		
APPLICANT NAME:	Shin, Yoonha		
ORGANIZATION:	The University of Texas Health Science Center at San Antonio		
PANEL NAME:	Basic Cancer Research 3		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	09/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/24/2018
	Method of submission	CARS	12/24/2018
	Within receipt period	YES	12/24/2018
	Request for extension to submit application after CARS closed	NA	12/24/2018
	Request for extension for late application submission accepted	NA	12/24/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/24/2018
	Donation(s) made to CPRIT / foundation	NO	12/24/2018
	Assigned to primary reviewers	08/02/2018	12/24/2018
	Applicant notified of review panel assignment	07/09/2018	12/24/2018
	Primary Reviewer 1 COI signed	06/12/2018	12/24/2018
	Primary Reviewer 2 COI signed	06/15/2018	12/24/2018
	Primary Reviewer 3 COI signed	07/13/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/18/2018	12/24/2018
	Primary Reviewer 2 critique submitted	08/22/2018	12/24/2018
	Primary Reviewer 3 critique submitted	08/20/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/24/2018
	COI indicated by non primary reviewer	NONE	12/24/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/24/2018
	Recommended for full review	YES	12/24/2018
	Applicant notified of outcome	09/28/2018	12/24/2018
Peer Review Meeting	Assigned to primary reviewers	08/02/2018	12/24/2018
	Primary Reviewer 1 COI signed	08/18/2018	12/24/2018
	Primary Reviewer 2 COI signed	10/05/2018	12/24/2018
	Primary Reviewer 3 COI signed	08/02/2018	12/24/2018
	Primary (Advocate) Reviewer 4 COI signed	07/31/2018	12/24/2018
	Primary Reviewer 1 critique submitted	10/10/2018	12/24/2018
	Primary Reviewer 2 critique submitted	10/15/2018	12/24/2018
	Primary Reviewer 3 critique submitted	10/11/2018	12/24/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/03/2018	12/24/2018
	COI indicated by non-primary reviewer	NONE	12/24/2018
	COI recused from participation	NA	12/24/2018
	Discussed at Peer Review Meeting	YES	12/24/2018
	Peer Review Meeting	10/19/2018	12/24/2018
	Post review statements signed	10/22/2018	12/24/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/24/2018
	Recommended for SRC review	YES	12/24/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/24/2018
	COI recused from participation	NA	12/24/2018
	SRC Meeting	12/05/2018	12/24/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/24/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190398
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:01 AM

FY:	2018
CYCLE:	1
PROGRAM:	Research
MECHANISM:	Individual Investigator Research Awards
APPLICATION ID:	RP180398
APPLICATION TITLE	Targeting the mechanism of hyperactive ERAS to transcriptional reprogramming toward endocrine resistance
APPLICANT NAME:	Schiff, Rachel
ORGANIZATION:	Baylor College of Medicine
PANEL NAME:	Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/03/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	06/02/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/19/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/03/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/19/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/07/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/13/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/21/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/23/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	Geoffrey Greene	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/23/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/06/2018	12/26/2018
	Primary Reviewer 1 COI signed	10/18/2018	12/26/2018
	Primary Reviewer 2 COI signed	10/12/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/20/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/01/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/17/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/17/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/13/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/03/2018	12/26/2018
	COI indicated by non-primary reviewer	Geoffrey Greene, Anne Tonachel	12/26/2018
	COI recused from participation	YES	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/12/2018	12/26/2018
	Post review statements signed	10/22/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	02/01/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190400
Individual Investigator Research Awards for
Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 37 applications in response to this RFA, including two applications that were withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer two award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:01 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards for Cancer in Children and Adolescents		
APPLICATION ID:	RP190600		
APPLICATION TITLE	Utilization of Imaging and Serum Biomarkers to Predict the Development of Cardiac Dysfunction		
APPLICANT NAME:	Noel, Cory V		
ORGANIZATION:	Baylor College of Medicine		
PANEL NAME:	Imaging Technology and Informatics		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/09/2018	12/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	12/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	12/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	12/01/2018
	Date application submitted	06/06/2018	12/10/2018
	Method of submission	CARS	12/10/2018
	Within receipt period	YES	12/10/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative science notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	07/21/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/26/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/19/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/18/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/17/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/20/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	09/10/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/03/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/02/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/10/2018	12/26/2018
	Primary Reviewer 2 critique submitted	09/30/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/09/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	09/24/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/18/2018	12/26/2018
	Post review statements signed	11/02/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC Member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP190417
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-2 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:01 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190432		
APPLICATION TITLE	Decoding the Pathogenic Roles of Non-Coding Variants in Hematopoietic Malignancies		
APPLICANT NAME:	Qin, Jun		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Basic Cancer Research-3		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/04/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	06/08/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/18/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/18/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	09/04/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/20/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/16/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/27/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/01/2018	12/26/2018
	Primary Reviewer 2 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/22/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/28/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/15/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/16/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/15/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/15/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/23/2018	12/26/2018
	Post review statements signed	10/25/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/09/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/09/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP190435
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Basic Cancer Research-2 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:01 AM

FY:	2019		
CYCLE:	II		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190435		
APPLICATION TITLE:	Modulating Cardiomyocyte DNA Damage in Response to Genotoxic Stress		
APPLICANT NAME:	Sadek, Hesham		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Basic Cancer Research 2		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/09/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
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	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
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	Primary Reviewer 3 COI signed	08/22/2018	12/26/2018
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	COI recused from participation	NA	12/26/2018
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Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP190451
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

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CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:01 AM

FY:	2018
CYCLE:	1
PROGRAM:	Research
MECHANISM:	Individual Investigator Research Awards
APPLICATION ID:	RP[redacted]
APPLICATION TITLE	Comprehensive evaluation of functional behaviors in breast cancer risk susceptibility [redacted]
APPLICANT NAME:	Hsin, Gary C
ORGANIZATION:	The University of Texas Southwestern Medical Center
PANEL NAME:	Cancer Prevention Research

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/05/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / Foundation	NO	12/26/2018
	Assigned to primary reviewers	08/03/2018	12/26/2018
	Applicant notified of review panel assignment	07/05/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/20/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/26/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/08/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/24/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/21/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/20/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/24/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/26/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/07/2018	12/26/2018
	Primary Reviewer 1 COI signed	08/24/2018	12/26/2018
	Primary Reviewer 2 COI signed	09/07/2018	12/26/2018
	Primary Reviewer 3 COI signed	08/02/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/08/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/24/2018	12/26/2018
	Primary Reviewer 2 critique submitted	09/17/2018	12/26/2018
	Primary Reviewer 3 critique submitted	09/25/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/15/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/24/2018	12/26/2018
	Post review statements signed	10/31/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/10/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/10/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / Foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP190454
Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 268 applications in response to this RFA, including seven applications that were withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as 'Final Scores for Fully Reviewed Applications.'

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Willson explained that each of CPRIT's scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The Program Integration Committee (PIC) unanimously voted to defer six award recommendations made by the Scientific Review Council for this mechanism to a future meeting date of the PIC. The decision resulted from the recommendation by the Chief Scientific Officer.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the

conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 11:01 AM

FY:	2019		
CYCLE:	1		
PROGRAM:	Research		
MECHANISM:	Individual Investigator Research Awards		
APPLICATION ID:	RP190054		
APPLICATION TITLE	Characterization of CTCF-mediated 3D genome organization and transcriptional regulation in ne		
APPLICANT NAME:	Main, Ram S		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Cancer Biology		
Category	Compliance Requirement	Information	Completion Date
Pre-Receipt	RFA Approved by CEO	01/05/2018	11/01/2018
	RFA published in Texas.gov eGrants	01/19/2018	11/01/2018
	CPRIT Application Receipt System (CARS) opened	03/07/2018	11/01/2018
	CPRIT Application Receipt System (CARS) closed	06/06/2018	11/01/2018
	Date application submitted	06/06/2018	12/26/2018
	Method of submission	CARS	12/26/2018
	Within receipt period	YES	12/26/2018
	Request for extension to submit application after CARS closed	NA	12/26/2018
	Request for extension for late application submission accepted	NA	12/26/2018
Receipt, Referral, and Assignment	Administrative review notification	NA	12/26/2018
	Donation(s) made to CPRIT / foundation	NO	12/26/2018
	Assigned to primary reviewers	08/02/2018	12/26/2018
	Applicant notified of review panel assignment	07/09/2018	12/26/2018
	Primary Reviewer 1 COI signed	06/15/2018	12/26/2018
	Primary Reviewer 2 COI signed	07/31/2018	12/26/2018
	Primary Reviewer 3 COI signed	06/12/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	06/07/2018	12/26/2018
Preliminary Evaluation	Primary Reviewer 1 critique submitted	08/18/2018	12/26/2018
	Primary Reviewer 2 critique submitted	08/18/2018	12/26/2018
	Primary Reviewer 3 critique submitted	08/20/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	NA	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	Preliminary Evaluation score summary sent to Chair	08/23/2018	12/26/2018
	Recommended for full review	YES	12/26/2018
	Applicant notified of outcome	09/28/2018	12/26/2018
Peer Review Meeting	Assigned to primary reviewers	09/06/2018	12/26/2018
	Primary Reviewer 1 COI signed	09/06/2018	12/26/2018
	Primary Reviewer 2 COI signed	10/16/2018	12/26/2018
	Primary Reviewer 3 COI signed	07/31/2018	12/26/2018
	Primary (Advocate) Reviewer 4 COI signed	08/07/2018	12/26/2018
	Primary Reviewer 1 critique submitted	10/19/2018	12/26/2018
	Primary Reviewer 2 critique submitted	10/18/2018	12/26/2018
	Primary Reviewer 3 critique submitted	10/14/2018	12/26/2018
	Primary (Advocate) Reviewer 4 critique submitted	10/02/2018	12/26/2018
	COI indicated by non-primary reviewer	NONE	12/26/2018
	COI recused from participation	NA	12/26/2018
	Discussed at Peer Review Meeting	YES	12/26/2018
	Peer Review Meeting	10/22/2018	12/26/2018
	Post review statements signed	10/22/2018	12/26/2018
	Third Party Observer Report	10/30/2018	01/03/2019
	Score report delivered to CSO	11/08/2018	12/26/2018
	Recommended for SRC review	YES	12/26/2018
Final SRC Recommendation	COI indicated by SRC member	NA	12/26/2018
	COI recused from participation	NA	12/26/2018
	SRC Meeting	12/05/2018	12/26/2018
	Third Party Observer Report	12/05/2018	01/03/2019
	Recommended for grant award	YES	12/26/2018
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NA	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	Created Date
Comment	
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RR190020
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Sangeetha Reddy, M.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received seven applications for cycles 19.4 through 19.6 in response to this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019		
CYCLE:	1		
PROGRAM:	Recruitment		
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members		
APPLICATION ID:	RR190020		
APPLICATION TITLE	Nomination of Sangeetha Reddy, MD, MSci for a CPRIT First-Time Tenure-Track Faculty		
APPLICANT NAME:	Thiele, Dwain L		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Recruitment FY19 Cycle 4-5		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/11/2018	09/28/2018
	RFA published in Texas.gov eGrants	08/06/2018	09/28/2018
	CPRIT Application Receipt Cycle opened	09/21/2018	01/09/2019
	CPRIT Application Receipt Cycle closed	11/20/2018	01/09/2019
	19.4 CPRIT Application Receipt Cycle opened	09/21/2018	01/09/2019
	19.4 CPRIT Application Receipt Cycle closed	10/22/2018	01/09/2019
	Date application submitted	10/19/2018	01/09/2019
	Method of submission	CARS	01/09/2019
	Within receipt period	YES	01/09/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/09/2019
	Donation(s) made to CPRIT / foundation	NO	01/09/2019
	Assigned to primary reviewers	11/30/2018	01/09/2019
	Applicant notified of review panel assignment	NA	01/09/2019
	Primary Reviewer 1 COI signed	11/26/2018	01/09/2019
	Primary Reviewer 2 COI signed	11/29/2018	01/09/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	12/11/2018	01/09/2019
	Primary Reviewer 2 critique submitted	12/11/2018	01/09/2019
	COI indicated by non-primary reviewer	NONE	01/09/2019
	COI recused from participation	NA	01/09/2019
	Discussed at Peer Review Meeting	YES	01/09/2019
	Peer Review Meeting	12/13/2018	01/09/2019
	Post review statements signed	12/21/2018	01/09/2019
	Third Party Observer Report	12/13/2018	01/09/2019
	Score report delivered to CSO	12/21/2018	01/09/2019
	Recommended for SRC review	YES	01/09/2019
Final SRC Recommendation	COI indicated by SRC member	NONE	01/09/2019
	COI recused from participation	NA	01/09/2019
	SRC Meeting	12/13/2018	01/09/2019
	Third Party Observer Report	12/13/2018	01/09/2019
	Recommended for grant award	YES	01/09/2019
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	02/06/2019
	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR190021
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Di Zhao, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received seven applications for cycles 19.4 through 19.6 in response to this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 02/07/2019 12:54 PM

FY:	2019
CYCLE:	1
PROGRAM:	Recruitment
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members
APPLICATION ID:	RR190021
APPLICATION TITLE	Recruitment of First-Time, Tenure-Track Faculty Members- Di Zhao
APPLICANT NAME:	Draetta, Giulio
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center
PANEL NAME:	Recruitment FY19 Cycle 4-5

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/11/2018	09/28/2018
	RFA published in Texas.gov eGrants	08/06/2018	09/28/2018
	CPRIT Application Receipt Cycle opened	09/21/2018	01/09/2019
	CPRIT Application Receipt Cycle closed	11/20/2018	01/09/2019
	19.4 CPRIT Application Receipt Cycle opened	09/21/2018	01/09/2019
	19.4 CPRIT Application Receipt Cycle closed	10/22/2018	01/09/2019
	Date application submitted	10/22/2018	01/09/2019
	Method of submission	CARS	01/09/2019
	Within receipt period	YES	01/09/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/09/2019
	Donation(s) made to CPRIT / foundation	NO	01/09/2019
	Assigned to primary reviewers	11/30/2018	01/09/2019
	Applicant notified of review panel assignment	NA	01/09/2019
	Primary Reviewer 1 COI signed	11/28/2018	01/09/2019
	Primary Reviewer 2 COI signed	11/26/2018	01/09/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	12/11/2018	01/09/2019
	Primary Reviewer 2 critique submitted	12/11/2018	01/09/2019
	COI indicated by non-primary reviewer	NONE	01/09/2019
	COI recused from participation	NA	01/09/2019
	Discussed at Peer Review Meeting	YES	01/09/2019
	Peer Review Meeting	12/13/2018	01/09/2019
	Post review statements signed	12/21/2018	01/09/2019
	Third Party Observer Report	12/13/2018	01/09/2019
	Score report delivered to CSO	12/21/2018	01/09/2019
	Recommended for SRC review	YES	01/09/2019
Final SRC Recommendation	COI indicated by SRC member	NONE	01/09/2019
	COI recused from participation	NA	01/09/2019
	SRC Meeting	12/13/2018	01/09/2019
	Third Party Observer Report	12/13/2018	01/09/2019
	Recommended for grant award	YES	01/09/2019
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	02/06/2019
	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RR190023
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Uri Ben-David, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received seven applications for cycles 19.4 through 19.6 in response to this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 02/07/2019 12:54 PM

FY:	2019
CYCLE:	1
PROGRAM:	Recruitment
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members
APPLICATION ID:	RR190023
APPLICATION TITLE	Recruitment of First-Time, Tenure-Track Faculty Members-Dr. Uri Ben-David
APPLICANT NAME:	Draetta, Gulio
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center
PANEL NAME:	Recruitment FY19 Cycle 4-5

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/11/2018	09/26/2018
	RFA published in Texas.gov eGrants	08/06/2018	09/28/2018
	CPRIT Application Receipt Cycle opened	09/21/2018	01/09/2019
	CPRIT Application Receipt Cycle closed	11/20/2018	01/09/2019
	19.5 CPRIT Application Receipt Cycle opened	10/23/2018	01/09/2019
	19.5 CPRIT Application Receipt Cycle closed	11/20/2018	01/09/2019
	Date application submitted	11/20/2018	01/09/2019
	Method of submission	CARS	01/09/2019
	Within receipt period	YES	01/09/2019
Receipt, Referral, and Assignment	Administrative review notification	11/26/2018	01/09/2019
	Donation(s) made to CPRIT / foundation	NO	01/09/2019
	Assigned to primary reviewers	11/30/2018	01/09/2019
	Applicant notified of review panel assignment	NA	01/09/2019
	Primary Reviewer 1 COI signed	11/28/2018	01/09/2019
	Primary Reviewer 2 COI signed	11/30/2018	01/09/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	11/30/2018	01/09/2019
	Primary Reviewer 2 critique submitted	12/11/2018	01/09/2019
	COI indicated by non-primary reviewer	NONE	01/09/2019
	COI recused from participation	NA	01/09/2019
	Discussed at Peer Review Meeting	YES	01/09/2019
	Peer Review Meeting	12/13/2018	01/09/2019
	Post review statements signed	12/21/2018	01/09/2019
	Third Party Observer Report	12/13/2018	01/09/2019
	Score report delivered to CSO	12/21/2018	01/09/2019
	Recommended for SRC review	YES	01/09/2019
Final SRC Recommendation	COI indicated by SRC member	NONE	01/09/2019
	COI recused from participation	NA	01/09/2019
	SRC Meeting	12/13/2018	01/09/2019
	Third Party Observer Report	12/13/2018	01/09/2019
	Recommended for grant award	YES	01/09/2019
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	02/06/2019
	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:

Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR190025
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Julian West, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received seven applications for cycles 19.4 through 19.6 in response to this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

Melanie Cleveland
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019		
CYCLE:	1		
PROGRAM:	Recruitment		
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members		
APPLICATION ID:	RR190025		
APPLICATION TITLE	Recruitment of First-Time, Tenure Track Faculty Member - Dr. Julian West		
APPLICANT NAME:	Rossky, Peter J		
ORGANIZATION:	Rice University		
PANEL NAME:	Recruitment FY19 Cycle 6		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/11/2018	09/28/2018
	RFA published in Texas.gov eGrants	08/06/2018	09/28/2018
	CPRIT Application Receipt Cycle opened	11/21/2018	01/21/2019
	CPRIT Application Receipt Cycle closed	12/20/2018	01/21/2019
	Date application submitted	12/17/2018	01/21/2019
	Method of submission	CARS	01/21/2019
	Within receipt period	YES	01/21/2019
Receipt, Referral, and Assignment	Administrative review notification	NA	01/21/2019
	Donation(s) made to CPRIT / foundation	NO	01/21/2019
	Assigned to primary reviewers	01/04/2019	01/21/2019
	Applicant notified of review panel assignment	NA	01/21/2019
	Primary Reviewer 1 COI signed	12/26/2018	01/21/2019
	Primary Reviewer 2 COI signed	12/26/2018	01/21/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	01/15/2019	01/21/2019
	Primary Reviewer 2 critique submitted	01/15/2019	01/21/2019
	COI indicated by non-primary reviewer	NONE	01/21/2019
	COI recused from participation	NA	01/21/2019
	Discussed at Peer Review Meeting	YES	01/21/2019
	Peer Review Meeting	01/17/2019	01/21/2019
	Post review statements signed	01/18/2019	01/21/2019
	Third Party Observer Report	01/17/2019	01/21/2019
	Score report delivered to CSO	01/21/2019	01/21/2019
	Recommended for SRC review	YES	01/21/2019
Final SRC Recommendation	COI indicated by SRC member	NONE	01/21/2019
	COI recused from participation	NA	01/21/2019
	SRC Meeting	01/17/2019	01/21/2019
	Third Party Observer Report	01/17/2019	01/21/2019
	Recommended for grant award	YES	01/21/2019
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	02/06/2019
	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR190027
Recruitment of Rising Stars
Nomination of Joshi Alumkal, M.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Rising Stars* Request for Applications (RFA). CPRIT received one application for cycles 19.4 through 19.6 in response to this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

Melanie Cleveland
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019		
CYCLE:	1		
PROGRAM:	Recruitment		
MECHANISM:	Recruitment of Rising Stars		
APPLICATION ID:	RR190027		
APPLICATION TITLE	Nomination of Joshi J. Alumkal, M.D. for a CPRIT Rising Stars Award		
APPLICANT NAME:	Thiele, Dwain L		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Recruitment FY19 Cycle 6		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/11/2018	09/28/2018
	RFA published in Texas.gov eGrants	07/25/2018	09/28/2018
	CPRIT Application Receipt Cycle opened	11/21/2018	01/21/2019
	CPRIT Application Receipt Cycle closed	12/20/2018	01/21/2019
	Date application submitted	12/17/2018	01/21/2019
	Method of submission	CARS	01/21/2019
	Within receipt period	YES	01/21/2019
Receipt, Referral, and Assignment	Administrative review notification	12/27/2018	01/21/2019
	Donation(s) made to CPRIT / foundation	NO	01/21/2019
	Assigned to primary reviewers	01/04/2019	01/21/2019
	Applicant notified of review panel assignment	NA	01/21/2019
	Primary Reviewer 1 COI signed	12/26/2018	01/21/2019
	Primary Reviewer 2 COI signed	01/02/2019	01/21/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	01/15/2019	01/21/2019
	Primary Reviewer 2 critique submitted	01/14/2019	01/21/2019
	COI indicated by non-primary reviewer	NONE	01/21/2019
	COI recused from participation	NA	01/21/2019
	Discussed at Peer Review Meeting	YES	01/21/2019
	Peer Review Meeting	01/17/2019	01/21/2019
	Post review statements signed	01/18/2019	01/21/2019
	Third Party Observer Report	01/17/2019	01/21/2019
	Score report delivered to CSO	01/21/2019	01/21/2019
	Recommended for SRC review	YES	01/21/2019
Final SRC Recommendation	COI indicated by SRC member	NONE	01/21/2019
	COI recused from participation	NA	01/21/2019
	SRC Meeting	01/17/2019	01/21/2019
	Third Party Observer Report	01/17/2019	01/21/2019
	Recommended for grant award	YES	01/21/2019
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	Candidate not accepted position prior to SRC date	YES	02/06/2019
	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR190029
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Ravikanth Maddipati, M.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received seven applications for cycles 19.4 through 19.6 in response to this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC members have approved conflict of interest waivers on file for FY2019: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3); and Dr. Becky Garcia, Chief Prevention Officer, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(1). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2019 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8th day of February, 2019, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 02/07/2019 12:54 PM

FY:	2019		
CYCLE:	1		
PROGRAM:	Recruitment		
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members		
APPLICATION ID:	RR190029		
APPLICATION TITLE	Nomination of Ravikanth Maddipati, M.D. for a CPRIT First-Time Tenure-Track Faculty M		
APPLICANT NAME:	Thiele, Owain L		
ORGANIZATION:	The University of Texas Southwestern Medical Center		
PANEL NAME:	Recruitment FY19 Cycle 6		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/11/2018	09/28/2018
	RFA published in Texas.gov eGrants	08/06/2018	09/28/2018
	CPRIT Application Receipt Cycle opened	11/21/2018	01/21/2019
	CPRIT Application Receipt Cycle closed	12/20/2018	01/21/2019
	Date application submitted	12/18/2018	01/21/2019
	Method of submission	CARS	01/21/2019
	Within receipt period	YES	01/21/2019
Receipt, Referral, and Assignment	Administrative review notification	12/27/2018	01/21/2019
	Donation(s) made to CPRIT / foundation	NO	01/21/2019
	Assigned to primary reviewers	01/04/2019	01/21/2019
	Applicant notified of review panel assignment	NA	01/21/2019
	Primary Reviewer 1 COI signed	01/02/2019	01/21/2019
	Primary Reviewer 2 COI signed	01/02/2019	01/21/2019
Peer Review Meeting	Primary Reviewer 1 critique submitted	01/15/2019	01/21/2019
	Primary Reviewer 2 critique submitted	01/15/2019	01/21/2019
	COI indicated by non-primary reviewer	NONE	01/21/2019
	COI recused from participation	NA	01/21/2019
	Discussed at Peer Review Meeting	YES	01/21/2019
	Peer Review Meeting	01/17/2019	01/21/2019
	Post review statements signed	01/18/2019	01/21/2019
	Third Party Observer Report	01/17/2019	01/21/2019
	Score report delivered to CSO	01/21/2019	01/21/2019
	Recommended for SRC review	YES	01/21/2019
Final SRC Recommendation	COI indicated by SRC member	NONE	01/21/2019
	COI recused from participation	NA	01/21/2019
	SRC Meeting	01/17/2019	01/21/2019
	Third Party Observer Report	01/17/2019	01/21/2019
	Recommended for grant award	YES	01/21/2019
	SRC Chair Notification to PIC and OC	01/24/2019	01/29/2019
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	02/06/2019
	COI indicated by PIC member	NONE	02/07/2019
	COI recused from participation	NA	02/07/2019
	PIC Review Meeting	02/07/2019	02/07/2019
	Recommended for grant award	YES	02/07/2019
Oversight Committee Approval	CEO Notification to Oversight Committee	NA	
	COI indicated by Oversight Committee member	NA	
	COI Recused from participation	NA	
	Donation(s) made to CPRIT / foundation	NA	
	Presented to CPRIT Oversight Committee	NA	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	NA	
	Advance authority approved by Oversight Committee	NA	

Comments:	
Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.