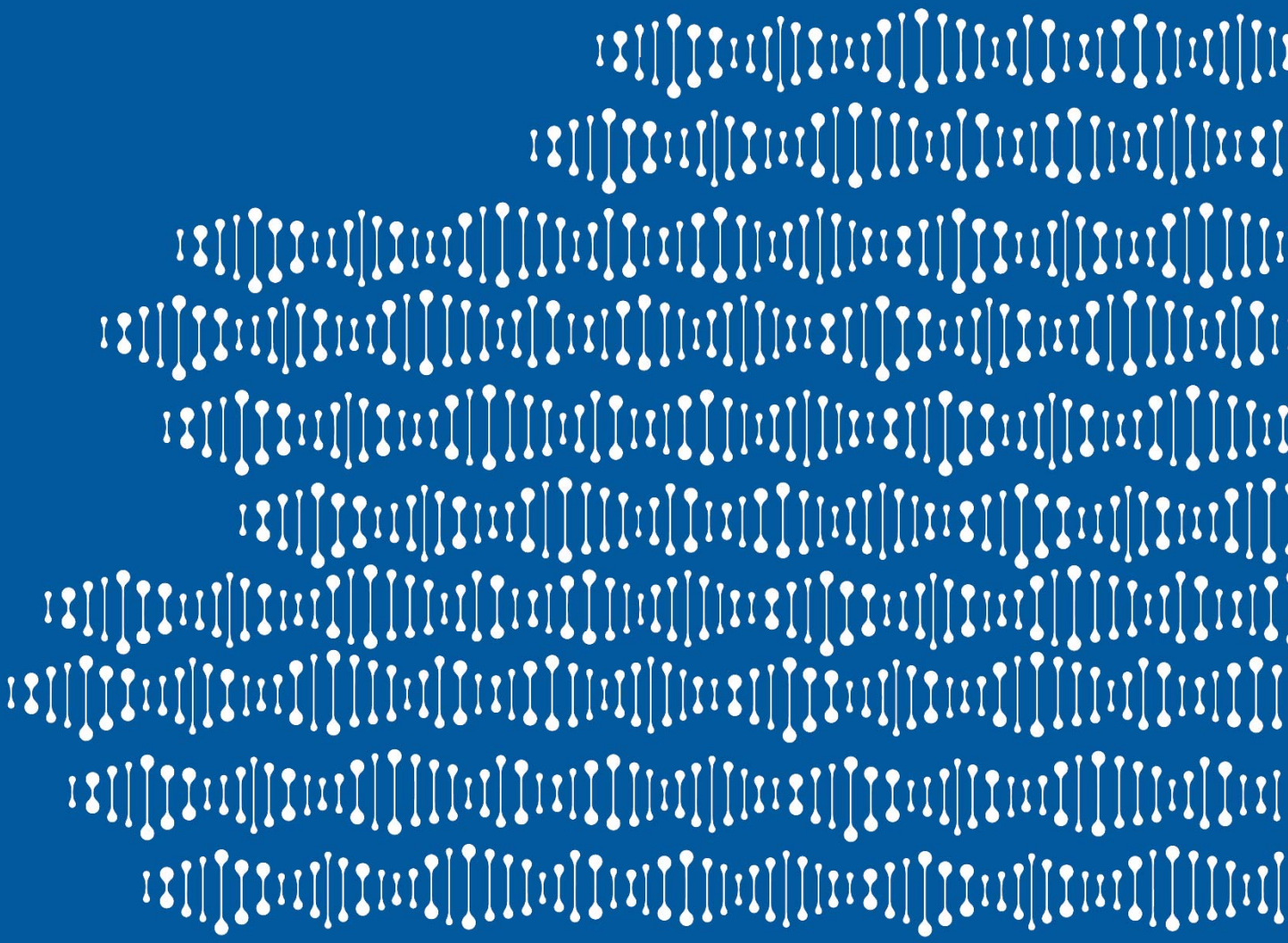
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Proposed Grant Awards

September 14, 2022



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: MICHELLE LE BEAU, PH.D., CPRIT CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH FY2022 REVIEW CYCLE 2, AND RECRUITMENT AWARD RECOMMENDATIONS FY2022, CYCLE 22.10

DATE: SEPTEMBER 14, 2022

The Scientific Review Council (SRC) and Program Integration Committee (PIC) recommendations for FY2022 review cycle 2 and recruitment cycle 22.10 include 25 awards from five grant mechanisms to 12 Texas Institutions totaling **$36,768,514.**

The following tables summarize the FY22.2 recommended applications and funding totals by Mechanism (Table 1), Institution (Table 2), and CPRIT Priority (Table 3).

Table 1: FY22.2 Recommended Applications by Mechanism

Grant Mechanism	SRC Recommendations	
	Awards	Funding
Early Clinical Investigator Award	2	$2,994,784
Core Facility Support Awards	6	$23,298,824
Clinical Trials Network Award	1	$3,000,000
High-Impact/High Risk Awards	14	$3,474,906
Recruitment of First-Time, Tenure-Track Faculty Members	2	$4,000,000
Total	**25**	**$36,768,514**

Table 2. FY22.2 Recommended Applications by Institution

Institution	SRC Recommendations	
	Awards	Funding
Baylor College of Medicine	2	$4,249,996
Rice University	1	$2,000,000
Texas A&M University System Health Science Center	1	$237,500
Texas Tech University	1	$249,999
Texas Tech University Health Sciences Center	1	$3,369,480
The Methodist Hospital Research Institute	2	$500,000
The University of Texas at Arlington	1	$250,000
The University of Texas at Austin	4	$6,495,110
The University of Texas Health Science Center at San Antonio	2	$7,934,168
The University of Texas M. D. Anderson Cancer Center	5	$2,499,975
The University of Texas Medical Branch at Galveston	1	$1,494,784
The University of Texas Southwestern Medical Center	4	$7,487,501
Total	**25**	**$36,768,514**

Table 3: Program Priorities Addressed

Program Priorities Addressed by Grant Recommendations		
# Awards*	Program Priorities	Funding*
2	Recruitment of Outstanding Cancer Researchers to Texas	$4,000,000
17	A Broad Range of Innovative, Investigator-Initiated Research Projects	$9,469,690
6	Investment in Core Facilities	$23,298,824
5	Childhood Cancers	$17,300,136
2	Population Disparities	$499,999
1	Hepatocellular Cancer	$237,501
3	Expand Access to Innovative Clinical Trials	$5,994,784
2	Computational biology and analytic methods	$7,998,688
10	Drug Discovery	$22,300,067
*Some grant awards address more than one program priority and are double counted.		

1. Core Facility Support Awards (RFA R-22.2 CFSA) Slate

Scientific Review Council Recommendations:
Out of 23 Core Facility Support (CFSA) grant applications submitted, the SRC recommended six, totaling $23,298,824.

Purpose of Core Facility Support Awards:
Solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with, and survivors of, cancer.

Core Facility Support Award Funding Levels:
Award: Up to $4M (total costs); Maximum duration: 5 years.

Recommended CFSA Institutions:
Baylor College of Medicine, Texas Tech University Health Sciences Center, The University of Texas Austin, The University of Texas Health Science Center San Antonio (2 awards), and The University of Texas Southwestern Medical Center.

Note that the awards are listed in order of the evaluation score.

RP220582
PI: Michael Rosen, Ph.D.
Title: Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UT Southwestern Medical Center
Applicant Organization: The University of Texas Southwestern Medical Center
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.0
Recommended Total Budget Award and Duration: $4,000,000
CPRIT Priorities Addressed: Investment in core facilities; Drug Discovery, Computational biology, and analytic methods

Description:
This is a renewal award to support and expand the cryo-electron microscopy (cryo-EM) Core Facility at the University of Texas Southwestern Medical Center. The productivity of the core is demonstrated by 69 publications from 150 users during the past support period and, new cancer-related research grants bringing $25.8M to user laboratories. The Facility also played a key role in recruiting 5 faculty and many postdocs and students to UTSW. Through this renewal, the UTSW cryo-EM program will use new hardware and software to accelerate the acquisition and analysis of cryo-EM data, speeding discovery and allowing protein machines to be studied in finer detail. These approaches can yield unprecedented information on protein structure in native

environments, revealing molecular and cellular defects in cancer and suggesting new drug targets.

RP220646
PI: Michael Lewis, Ph.D.
Title: Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas
Applicant Organization: Baylor College of Medicine
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.8
Recommended Total Budget Award and Duration: $3,999,996
CPRIT Priorities Addressed: Investment in core facilities, Childhood Cancers, Drug Discovery

Description:
This is a renewal award to support specialized resources at Baylor College of Medicine to continue the production of "patient-derived xenografts" (PDX), in which human tumors are typically grown in immunocompromised mice. The Core currently provides PDX development, and experimental assistance to 18 PDX Programs, including 16 at BCM/TCH, and one each at the Huntsman Cancer Institute (Utah), and the University of Basel (Switzerland). In the new award, BCM will extend services to five new Texas institutions for a total of seven. These are: Baylor College of Medicine (BCM), Texas Children's Hospital (TCH), MD Anderson Cancer Center (MDACC), UT Austin, UT Southwestern (UTSW), UT San Antonio, and Texas Tech University Health Sciences Centers in collaboration with the Childhood Oncology Group. New goals are to provide computational and experimental infrastructure, as well as technical expertise to harmonize PDX programs across Texas.

RP220662
PI: Yidong Cheng, Ph.D.
Title: UTHSCSA Cancer Genome Sequencing and Computation Core
Applicant Organization: The University of Texas Health Science Center at San Antonio
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.9
Recommended Total Budget Award and Duration: $3,998,688
CPRIT Priorities Addressed: Investment in core facilities, Computational biology, and analytic methods

Description:
This is a renewal award to expand and enhance the existing infrastructure of the Cancer Genome Sequencing and Computation Core (CGSCC) at the University of Texas Health San Antonio (UTHSA). The productivity of the CGSCC is underscored by use of the core by 65 cancer researchers and 80 NCI/CPRIT research grants with total external funding exceeding $120 million, and contributing to greater than 80 peer-reviewed scientific publications. In the new award, UTHSC SA will introduce "third-generation sequencing" technology matched with enhanced data storage capability, to enable the detection of rare genetic variations at the single-molecule level from their unique patient population. The facility plans to significantly enhance the Core's single-cell library preparation capability up to a million cells per run, and to introduce

spatial transcriptomic techniques that will allow researchers to analyze single-cell gene expression in a wider variety of tissue samples, to reveal the cellular and spatial organization of tumors.

RP220631
PI: Min Kang, PharmD
Title: West Texas Pharmacology Core
Applicant Organization: Texas Tech University Health Sciences Center
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.9
Recommended Total Budget Award and Duration: $3,369,480
CPRIT Priorities Addressed: Investment in core facilities, Drug Discovery, and Childhood Cancers

Description:
This new core will serve two purposes. One is helping academic researcher's and biotech companies to develop new anti-cancer drugs. The other is promoting discoveries in new therapies for childhood cancers. One of the critical components of drug development is to study how the drug behaves in humans, especially in cancer patients. This is especially important to eliminate those drug candidates that won't make it as drugs before they are tested in cancer patients as human studies are very costly, and they may not help the patients. Pharmacology is one of the critical components in making" go-no-go" decisions on drug candidates and, thus, it is required to conduct such studies. However, many academic researchers and small biotech companies have limited access to pharmacology services due to the expertise required and resources required. Also, recent changes in federal law mandate biotech companies to develop drugs for childhood cancers. The Texas Tech University Health Science Center team of researchers is highly experienced in developing drugs from laboratory science to clinical trials, especially in childhood cancers. The team's expertise in pharmacology will help cancer researchers and biotech companies in Texas develop their drug candidates.

RP220599
PI: Peter Houghton, Ph.D.
Title: Texas Pediatric Cancer Testing (TPCT) Core
Applicant Organization: The University of Texas Health Science Center at San Antonio
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.3
Recommended Total Budget Award and Duration: $3,935,480
CPRIT Priorities Addressed: Investment in core facilities, Childhood Cancers, Drug Discovery

Description:
This is a renewal award to expand services for testing new agents/combinations, against a large panel (~400) of molecularly characterized Patient Derived Xenografts (PDXs; childhood cancers grown in mice) representing both childhood and adolescent/young adult hematologic and solid malignancies. The Core will facilitate pediatric cancer drug development within the context of the Research to Accelerate Cures and Equity for Children Act. The Act requires the Food and

Drug Administration (FDA) to develop a list of molecular targets of known and new drugs/biologics. If agents are determined to be substantially relevant to the growth and progression of pediatric cancer, this may trigger the requirement for pediatric investigations by both Pharma and academic centers. Unique aspects of this Core are (1) Bioinformatics-driven selection of molecularly appropriate tumor models; and (2) PDX models that encompass the molecular heterogeneity of a cancer type.

RP220587
PI: Jennifer Maynard, Ph.D.
Title: Advanced Protein Therapeutics Core
Applicant Organization: The University of Texas at Austin
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.3
Recommended Total Budget Award and Duration: $3,995,180
CPRIT Priorities Addressed: Investment in core facilities. Drug Discovery, Childhood Cancers

Description:
Recognizing that over 80 percent of FDA-approved therapies are originally derived from academic research, this new core facility, the Advanced Protein Therapeutics (APT) core facility aims to leverage Texas' historic strengths in cancer research by catalyzing translation of scientific discoveries into novel therapies. The purpose of this core facility is to make these capabilities more broadly available to anti-cancer researchers across Texas. This is expected to increase the number of new drug candidates reaching pre-clinical testing stages in Texas while possessing the potency, selectivity, and pharmacokinetic parameters necessary to effectively engage oncogenic targets and inhibit tumors. The physicians and scientists planning to take advantage of this program are exploring novel mechanisms to disrupt devastating diseases, including breast, liver, lung and pancreatic cancers and glioblastoma. Research supported by the APT will directly impact the development of new therapies for these and many other difficult-to-treat cancers.

2. Early Clinical Investigator Award (RFA R-22.2 ECI) Slate

Scientific Review Council Recommendations:
Out of six Early Clinical Investigator (ECI) grant applications submitted, the SRC recommended two totaling $2,994,784.

Purpose of Early Clinical Investigator Award:
Solicits applications from institutions to provide cancer physicians early in their academic career the opportunity to develop clinical research skills and to gain experience in advanced methods and experimental approaches needed to become clinical investigators. The award is designed to protect time from clinical responsibilities to allow the early clinical investigator to develop and conduct an investigator initiated clinical trial and to establish a partnership with a laboratory-based collaborator in order to conduct the correlative studies needed to interpret the outcome of the trial. The overall goal of this mechanism is to increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, capitalizing on basic discoveries, and translating them through conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.

Early Clinical Investigator Award Funding Levels:
Award: Up to $1,5000,000 (total costs); Maximum duration: 5 years

Recommended ECI Institutions: The University of Texas M.D. Anderson Cancer Center and the University of Texas Medical Branch at Galveston.

RP220544
PI: Christopher Alvarez-Breckenridge, M.D., Ph.D.
Title: CPRIT Early Clinical Investigator Award-Christopher Alvarez-Breckenridge
Applicant Organization: The University of Texas M. D. Anderson Cancer Center
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.8
Recommended Total Budget Award and Duration: $1,500,000
CPRIT Priorities Addressed: A broad range of innovative, investigator-initiated research projects; Expand access to innovative clinical trials.

Description:
Christopher Alvarez-Breckenridge, M.D., Ph.D., is an Assistant Professor in the Department of Neurosurgery, Division of Surgery at the University of Texas M.D. Anderson Cancer Center. He completed his combined M.D./Ph.D. training at The Ohio State University. His research on brain tumors began during his Ph.D. studies under the mentorship of E. Antonio Chiocca M.D., Ph.D., a pioneer in oncolytic viral therapy for glioblastoma and the current chair of Neurosurgery at Brigham and Women's Hospital, and Michael Caligiuri, M.D., an expert in natural killer (NK)

cell biology across multiple oncologic contexts and the current president of City of Hope National Medical Center. His Early Clinical Investigator award plan is to build upon his prior research experiences and develop the foundational discoveries needed for his goal of becoming an independently funded neurosurgeon-scientist. He plans to utilize clinically relevant melanoma brain metastasis models to perform in-depth characterization of the Delta-24-RGDOX oncolytic virus, which will culminate in a first-of its-kind clinical trial for patients with melanoma brain metastases. Frederick F. Lang, M.D., a recognized leader in the field of neurosurgery with particular focus on deep-seated brain tumors located in eloquent brain regions will serve as Dr. Alvarez-Breckenridge's primary mentor. Juan Fueyo, M.D., a Professor in the Department of Neuro-Oncology at M.D. Anderson and also the Scientific Director of Laboratory Research for the Brain Tumor Center and Candelaria Gomez-Manzano, M.D., a Professor in the Department of Neuro-Oncology at M.D. Anderson who serves as co-leader of the GBM Moonshot program, will serve as co-mentors.

RP220581
PI: Pablo Valdes, M.D., Ph.D.
Title: Hyperspectral, Quantitative Intraoperative Fluorescence Image-Guided Brain Surgery
Applicant Organization: The University of Texas Medical Branch at Galveston
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.1
Recommended Total Budget Award and Duration: $1,494,784
CPRIT Priorities Addressed: A broad range of innovative, investigator-initiated research projects; Expand access to innovative clinical trials.

Description:
Pablo Valdes, M.D., Ph.D., is Assistant Professor in the Department of Neurosurgery, with a dual appointment in the Department of Neuroscience, Cell Biology, and Anatomy, and with a clinical practice focused on neurosurgical oncology at UTMB. Dr. Valdes received his M.D. from Dartmouth Medical School (Geisel School of Medicine at Dartmouth) and a Ph.D., from Dartmouth's Thayer School of Engineering in Engineering Sciences. He did his neurosurgical residency and training at Harvard Medical School/Brigham and Women's/Boston Children's Hospitals, and completed a dedicated neurosurgical oncology and brain mapping fellowship at Montpellier University, France with Professor Hugues Duffau, M.D., Ph.D. Early Clinical Investigator award timeline: In the first year, he will develop a new infrared fluorescent imaging system for intraoperative detection of a tumor. In Year 2, he will then validate the system in in vitro and in vivo animal studies to include safety studies. In Year 3, he will conduct an animal clinical trial with rodent models to determine feasibility of a trial in humans. In Year 4, he will conduct the single-arm trial and will accrue 80% of the necessary patients to the trial. In Year 5, he will finish the phase 2 trial and additional preclinical studies in preparation for the clinical trial. His mentorship team includes Dr Kan, Chair of Neurosurgery at UTMB; Dr Ashok Veeraraghavan, who is an expert in hyperspectral technology at Rice University; and Dr Frederic Leblond from France, an expert in near-infrared and short-wave infrared spectroscopy.

3. Clinical Trials Network Award (RFA R-22.2 CTNA) Slate

Scientific Review Council Recommendations:
Out of two Clinical Trials Network Award (CTNA) grant applications submitted, the SRC recommended one totaling $3,000,000.

Purpose of Clinical Trials Network Award:
The Clinical Trials Network Award is designed to provide support to Texas cancer centers with established clinical trials infrastructure and clinical trials portfolio to develop and oversee a network of cancer care facilities that currently have limited access to clinical trials. The award is designed to support 2 network affiliates (stage 1) and once an initial network is satisfactorily demonstrated, the Lead Institution will be eligible to expand its network to two additional facilities located outside its current catchment area (stage 2).

Clinical Trials Network Award Funding Levels:
Award: Up to $600,000 annually for stage 1 and up to $900,000, annually for stage 2; Maximum duration: 5 years

Recommended CTNA Institution: The University of Texas Southwestern Medical Center

RP220542
PI: Muhammad Beg, M.D., M.S.
Title: Establish the Accelerating Clinical Oncology Research Network-Texas (ACORN-TX) to Enhance Clinical Trial Access in North and Central Texas
Applicant Organization: The University of Texas Southwestern Medical Center
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.9
Recommended Total Budget Award and Duration: $3,000,000
CPRIT Priorities Addressed: Expand access to innovative clinical trials.

Description:
The Simmons Comprehensive Cancer Center (SCCC) at UT Southwestern Medical Center, an NCI-designated cancer center will serve as the lead institution for the establishment of a clinical trials network to provide access to therapeutic clinical cancer trials to underrepresented patients in North and Central Texas. Stage I Network Affiliates include regional sites including UTSW affiliates Children's Health and Parkland Health and Hospital System, the safety-net provider of Dallas County, Baylor Scott and White, Temple Campus and John Peter Smith Hospital, the safety net providers in Tarrant County (Fort Worth). The Stage II Network Affiliate (NA) sites include Baylor Scott & White in College Station, Waxahachie, and the Hendrick Medical Center in Abilene. All affiliates serve vulnerable populations with barriers to healthcare including individuals who are low-income, un/underinsured, or from racial/ethnic minority groups. The goal of this award is to enhance clinical trial access for patients belonging to rural areas, and

those who belong to ethnic and racial monitory backgrounds. ACORN-TX will prioritize phase 2 and 3 clinical trials.

4. HIGH IMPACT/HIGH RISK RESEARCH AWARDS (RFA R-22.2 HIHR) SLATE

Scientific Review Council Recommendations:
Out of 89 High Impact/High Risk research award grant applications submitted, the SRC recommended 14, totaling $3,474,906.

Purpose of High Impact/High Risk Research Awards:
Provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.

High Impact/High Risk Research Award Funding Levels:
Up to $250,000 (total costs); Maximum duration: 2 years.

Recommended HIHR Institutions (8): Baylor College of Medicine, Texas A&M University System Health Science Center, Texas Tech University, The Methodist Hospital Research Institute, The University of Texas at Arlington, The University of Texas at Austin, The University Texas M.D. Anderson Cancer Center, and The University of Texas Southwestern Medical Center

Table 1: *High Impact/High Risk Research Awards Recommended for Funding. Note that awards are listed in order of the evaluation score.

ID	Score	Application Title	PI	PI Organization	Budget	Priority Addressed
RP220606	1.9	Developing a Novel Optogenetic Recombinase System to Study and Target Metastatic Cancer	Ravikanth Maddipati, Ph.D.	The University of Texas Southwestern Medical Center	$250,000	
RP220650	1.9	Targeting Nitric Oxide Synthase (NOS) Pathway to Remodel Obesity-Induced Tumor Inflammation in Patients With TNBC	Jenny Chang, Ph.D.	The Methodist Hospital Research Institute	$250,000	Disparities
RP220626	2.0	A Glia-to-Neuron Conversion for Treating Oral Cancer Pain	Feng Tao, M.D., Ph.D.	Texas A&M University System Health Science Center	$237,500	

RP220558	2.0	Novel Covalent Drugs for BCL6	Walter Fast, Ph.D.	The University of Texas at Austin	$249,999	Drug Discovery and Disparities
RP220614	2.0	Understanding the Impact of Immunity on Premalignant Somatic Mosaicism and Cancer Prevention	Hao Zhu, M.D.	The University of Texas Southwestern Medical Center	$237,501	Hepatocellular Cancer
RP220666	2.0	Targeting Tumors and the Tumor Microenvironment With Banana Lectin-Expressing T Cells	Katie McKenna, Ph.D.	Baylor College of Medicine	$250,000	
RP220567	2.0	Fasting-Induced Microbiome Changes and Radioprotection	Helen Piwnica-Worms, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$249,999	
RP220645	2.0	Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy	Georgios Alexandrakis, Ph.D.	The University of Texas at Arlington	$250,000	
RP220653	2.3	Novel Modulators of Genomic Instability in Human Cells	Karen Vasquez, Ph.D.	The University of Texas at Austin	$249,932	Drug Discovery
RP220592	2.4	Restoration of Phagocytosis Function of Glioma-Associated Microglia/Macrophage by Activating QKI-PPARb-RXRa	Jian Hu, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$250,000	Drug Discovery
RP220600	2.4	In Vivo Akt Analysis via Chemical Genetics and Nanoparticle-Mediated Probe Delivery	Degeng Wang, Ph.D.	Texas Tech University	$249,999	
RP220610	2.8	Identification of Enhancers of T-Cell Antitumor Activity in PDAC Using CRISPR Activation Screening	Anirban Maitra, MBBS	The University of Texas M. D. Anderson Cancer Center	$250,000	
RP220553	2.9	Reversing Aging-Associated Resistance to Cancer Immunotherapy	Wen Jiang, M.D., Ph.D.	The University of Texas M. D. Anderson Cancer Center	$249,976	
RP220639	2.9	Targeting NHE6 to Improve Clinical Efficacy of Daratumumab in Myeloma	Jing Yang, DrPH	The Methodist Hospital Research Institute	$250,000	Drug Discovery

*All High-Impact/High Risk Awards meet the following priority: A broad range of innovative, investigator-initiated research projects

5. RECRUITMENT FIRST-TIME TENURE TRACK FACULTY MEMBERS SLATE FY22.10

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:
Twelve Recruitment of First-Time Tenure Track Faculty Members grant applications were submitted and five were recommended by the Scientific Review Council for an award. RR220108 was withdrawn by the Institution and applications RR220094 and RR220101 were approved for funding by the Oversight Committee at the August 17, 2022 meeting.

Recommended Recruitment of First-Time Tenure Track Faculty Members: The University of Texas at Austin and Rice University.

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

RR220097
Candidate: Jennifer Kong, Ph.D.
Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member
Applicant Organization: The University of Texas at Austin
Original Organization of Nominee: Stanford University School of Medicine
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, Childhood Cancers

Description:
Jennifer Kong, PhD is nominated by UT Austin for a CPRIT First-Time, Tenure-Track Faculty Member Award, and appointment as an Assistant Professor in the Department of Molecular Biosciences. In the developing embryo, the Hedgehog (Hh) signaling pathway plays a critical

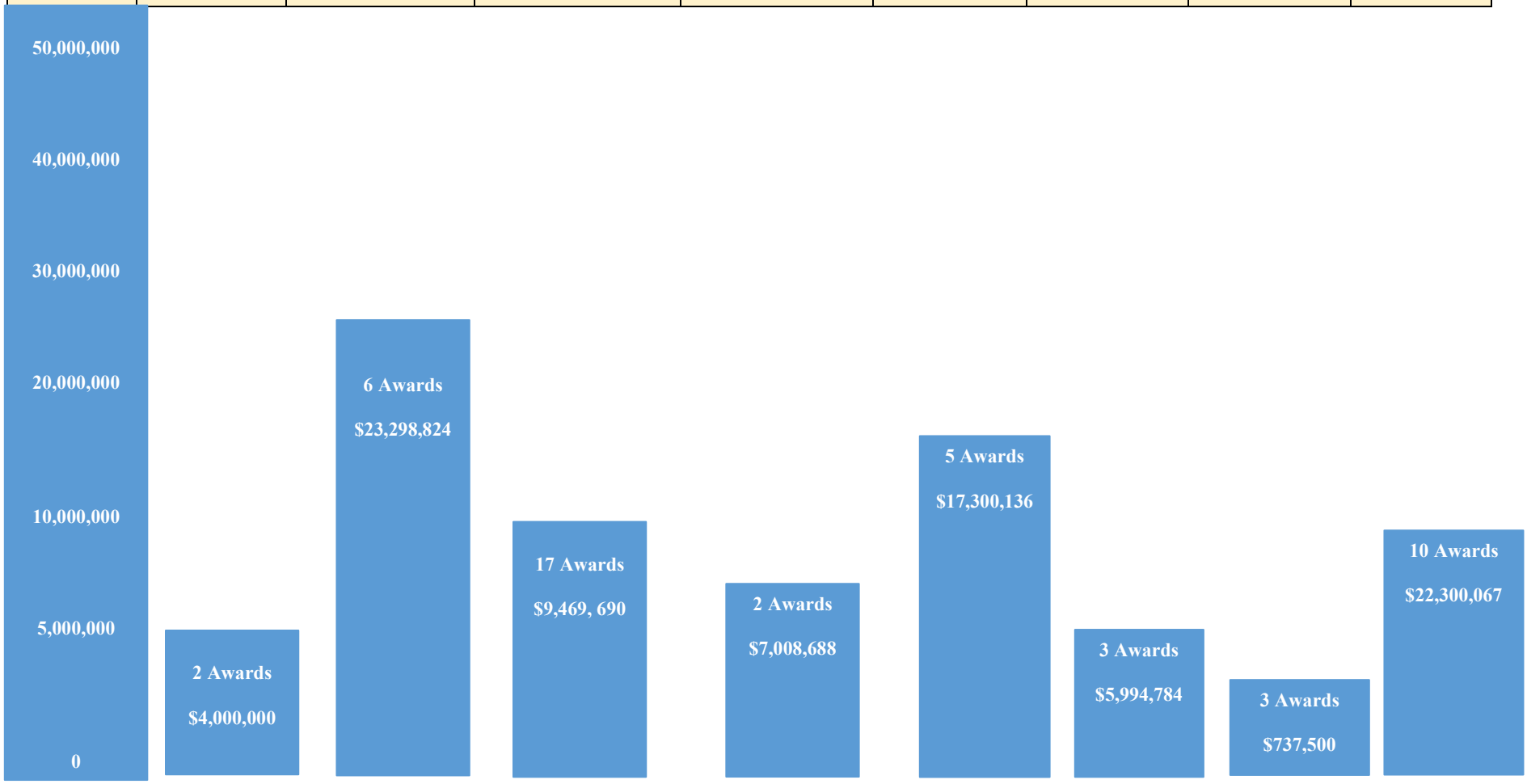
role in the formation of the neural system. However, inappropriate activation of Hh signaling within stem cell populations of the postnatal brain can initiate the formation of cancers, such as medulloblastoma, the most common malignant pediatric brain tumor. Although Hh-driven cancers often initially respond well to Hh inhibitors, over time cells become drug-resistant and the tumor returns. With support from an NIH Pathway to Independence K99/R00 award, Dr. Kong has developed a novel, unbiased genome-wide screening assay using CRISPR gene editing, and identified three proteins that act as attenuators of the Hh pathway in neural stem cells. Her research will expand upon this work to assess new molecular treatment strategies, designed to target these regulatory modules. In addition, she will use a quantitative proteomics approach to identify new mechanisms that can be used to suppress Hh pathway activity in drug-resistant medulloblastoma.

RR220092
Candidate: Emma Chory, Ph.D.
Funding Mechanism: Recruitment of First Time Tenure Track Faculty Member
Applicant Organization: Rice University
Original Organization of Nominee: Massachusetts Institute of Technology
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, Drug Discovery

Description:
Rice University is nominating Emma Chory, PhD for a CPRIT First-Time, Tenure-Track Faculty Member Award, as well as appointment as an Assistant Professor in the Department of Bioengineering. Dr. Chory is an unusual scientist in that she has training in the interdisciplinary fields of chemical engineering, synthetic biology, robotics, and epigenome engineering. In her previous work, she has employed directed evolution of small peptides to discover new therapies that target "undruggable" altered proteins in cancer. Directed engineering technology is the engineering of new biomolecules by recreating the processes of mutation, selection, and replication in the laboratory. Her CPRIT research will be focused on applying high throughput evolution to discover new peptides for cancer therapy, and to engineer precision biologic tools to modulate the epigenome for cancer research. The long-term goal of this research is to combine directed evolution, high throughput robotics, and synthetic chromatin biology to engineer novel precision biologics for cancer therapy.

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	Investment in Core Facilities	A broad range of innovative, investigator-initiated research projects	Computational biology and analytic methods	Childhood cancers	Expand Access to innovative clinical trials	Disparities and Hepatocellular Cancer	Drug Discovery



MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MICHELLE LE BEAU, PH.D., CPRIT CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH RECRUITMENT AWARD RECOMMENDATIONS FY2022, CYCLE 22.10
DATE:	SEPTEMBER 7, 2022

The Scientific Review Council (SRC) and Program Integration Committee (PIC) recommended two Recruitment Applications from Cycle 22.10 (RR220097 and RR220092) totaling $4,000,000. Both applications were withdrawn by the respective institutions, post the PIC meeting.

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

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September 1, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

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

Dear Dr. Patel and Mr. Roberts,

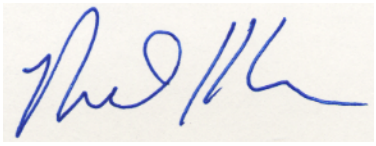
The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Early Clinical Awards, Core Facility Support Awards, Clinical Trials Network Award and High-Impact/Hight Risk Awards.

The SRC met on September 1, 2022 to consider the applications recommended by the peer review panels following their meetings held April 26, 2022 to May 5, 2022.

Recommended funding amounts and the overall evaluation score are stated for each grant application The total amount for the applications recommended is $32,768,514.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing CPRIT's long term goals to achieve a decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products.

Sincerely yours,



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

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

ID	Award RFA	Score	Application Title	PI	PI Organization	Recommended Budget
RP220582	CFSA	1.0	Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UTSouthwestern Medical Center	Rosen, Michael	The University of Texas Southwestern Medical Center	$4,000,000
RP220646	CFSA	1.8	Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas	Lewis, Michael	Baylor College of Medicine	$3,999,996
RP220544	ECI	1.8	CPRIT Early Clinical Investigator Award-Christopher Alvarez-Breckenridge	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,500,000
RP220606	HIHRRA	1.9	Developing a Novel Optogenetic Recombinase System to Study and Target Metastatic Cancer	Maddipati, Ravikanth	The University of Texas Southwestern Medical Center	$250,000
RP220662	CFSA	1.9	UTHSCSA Cancer Genome Sequencing and Computation Core	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$3,998,688
RP220650	HIHRRA	1.9	Targeting Nitric Oxide Synthase (NOS) Pathway to Remodel Obesity-Induced Tumor Inflammation in Patients With TNBC	Chang, Jenny	The Methodist Hospital Research Institute	$250,000
RP220631	CFSA	1.9	West Texas Pharmacology Core	Kang, Min	Texas Tech University Health Sciences Center	$3,369,480
RP220542	CTNA	1.9	Establish the Accelerating Clinical Oncology Research Network-Texas (ACORN-TX) to Enhance Clinical Trial Access in North and Central Texas	Beg, Muhammad	The University of Texas Southwestern Medical Center	$3,000,000
RP220626	HIHRRA	2.0	A Glia-to-Neuron Conversion for Treating Oral Cancer Pain	Tao, Feng	Texas A&M University System Health Science Center	$237,500

RP220558	HIHRRA	2.0	Novel Covalent Drugs for BCL6	Fast, Walter	The University of Texas at Austin	$249,999
RP220614	HIHRRA	2.0	Understanding the Impact of Immunity on Premalignant Somatic Mosaicism and Cancer Prevention	Zhu, Hao	The University of Texas Southwestern Medical Center	$237,501
RP220666	HIHRRA	2.0	Targeting Tumors and the Tumor Microenvironment With Banana Lectin-Expressing T Cells	McKenna, Katie	Baylor College of Medicine	$250,000
RP220567	HIHRRA	2.0	Fasting-Induced Microbiome Changes and Radioprotection	Piwnica-Worms, Helen	The University of Texas M. D. Anderson Cancer Center	$249,999
RP220645	HIHRRA	2.0	Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy	Alexandrakis, Georgios	The University of Texas at Arlington	$250,000
RP220581	ECI	2.1	Hyperspectral, Quantitative Intraoperative Fluorescence Image-Guided Brain Surgery	Urban, Randall	The University of Texas Medical Branch at Galveston	$1,494,784
RP220599	CFSA	2.3	Texas Pediatric Cancer Testing (TPCT) Core	Houghton, Peter	The University of Texas Health Science Center at San Antonio	$3,935,480
RP220653	HIHRRA	2.3	Novel Modulators of Genomic Instability in Human Cells	Vasquez, Karen	The University of Texas at Austin	$249,932
RP220587	CFSA	2.3	Advanced Protein Therapeutics Core	Maynard, Jennifer	The University of Texas at Austin	$3,995,180
RP220592	HIHRRA	2.4	Restoration of Phagocytosis Function of Glioma-Associated Microglia/Macrophage by Activating QKI-PPARb-RXRa	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	$250,000
RP220600	HIHRRA	2.4	In Vivo Akt Analysis via Chemical Genetics and Nanoparticle-Mediated Probe Delivery	Wang, Degeng	Texas Tech University	$249,999
RP220610	HIHRRA	2.8	Identification of Enhancers of T-Cell Antitumor Activity in PDAC Using CRISPR Activation Screening	Maitra, Anirban	The University of Texas M. D. Anderson Cancer Center	$250,000

RP220553	HIHRRA	2.9	Reversing Aging-Associated Resistance to Cancer Immunotherapy	Jiang, Wen	The University of Texas M. D. Anderson Cancer Center	$249,976
RP220639	HIHRRA	2.9	Targeting NHE6 to Improve Clinical Efficacy of Daratumumab in Myeloma	Yang, Jing	The Methodist Hospital Research Institute	$250,000

CFSA – Core Facility Support Awards
CTNA - Clinical Trials Network Awards
ECI – Early Clinical Investigator Awards
HIHRA – High-Impact/High Risk Awards

LUDWIG CANCER RESEARCH

San Diego

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Ludwig Institute for Cancer Research Ltd

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September 1, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

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

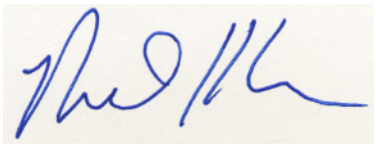
Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on on September 1, 2022 to review and finalize the (REC Cycle 22.10) applications submitted to CPRIT under the Recruitment of First-Time, Tenure Track Faculty Members RFA mechanism.

The SRC recommends two applications, which are inlcuded on the attached list. The recommended funding amounts and the overall evaluation scores are stated for the grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $4,000,000

The recommendation meets the SRC's standards for funding. These include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, 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

LUDWIG CANCER RESEARCH

San Diego

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Rank	App. ID	Mechanism	Candidate	Organization	Budget	Overall Scores
1	RR220097	RFTFM	Jennifer Kong, Ph.D.	The University of Texas at Austin	$2,000,000	1.6
2	RR220092	RFTFM	Emma Chory, Ph.D.	Rice University	$2,000,000	2.0

RFTFM = Recruitmen of First-Time, Tenure Track Faculty Members

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: KEN SMITH, PHD, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject: SEPTEMBER PRODUCT DEVELOPMENT RESEARCH AWARD RECOMMENDATION
Date: SEPTEMBER 1, 2022

Summary of Recommendation:

The Product Development Review Council (PDRC) recommends that the Program Integration Committee (PIC) and the Oversight Committee approve a product development research award to ImmuneSensor Therapeutics, Inc. The table below reflects the award recommendation, including the maximum recommended funding amount and the evaluation score.

The PDRC reviewed the ImmuneSensor application during the second cycle of the FY 2022 review process. However, due to CPRIT budgetary constraints and the PDRC's need for clarification on key points raised in the due diligence review, the PDRC left the application pending a final recommendation. The company updated the PDRC satisfactorily.

The PDRC did not make any changes to timelines or budgets for the project recommended for funding. However, I will address the proposed contingencies at the meetings with the PIC and the Oversight Committee

FY 2022 Cycle 2 Award Recommendations

Rank	ID	RFA	Company	Project	Score*	Budget
NA	DP220030	TXCO	ImmuneSensor Therapeutics, Inc.	Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of IMSA101 in Combination with Radiotherapy and Checkpoint Inhibitors in Solid Tumor Malignancies	3.5	$16,154,562
					TOTAL	**$ 16,154,562**

* - Average of reviewers' scores following company presentation peer review meeting

Background - FY 2022 Review Cycle 2

CPRIT released three product development RFAs in October 2021 for the second review cycle of FY 2022. CPRIT opened the application portal on December 1, 2021, and received 34 proposals by the January 26 deadline. Peer review panels met March 21 – 22 and selected 15 companies to present proposed projects live via Zoom April 11 - 14. Following company presentations, the review panels selected 11 companies to move into due diligence review by the PDRC. The

PDRC met July 13, 14, and 19 to review the due diligence reports and make final award recommendations for FY 2022 awards. The PDRC also met August 18 and August 30 to discuss the updated information provided by ImmuneSensor. Following those discussions, the PDRC convened a meeting by electronic mail on September 1 to approve a final award recommendation for ImmuneSensor.

PDRC Chair Dr. Jack Geltosky noted in his letter to the PIC and the Oversight Committee that the PDRC's recommendation to fund this award reflected 50+ hours of individual review and panel discussion for the application as well as the PDRC's review of the diligence materials for the company.

Product Development Research Priorities Addressed by the Proposed Award

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

Applications Addressing Priorities	Product Development Research Priorities	Award Amount per Priority
1	Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies	**$16,154,562**
1	Funding projects addressing large or challenging unmet medical needs	**$16,154,562**
1	Investing in early-stage projects where private capital is least available	**$16,154,562**
1	Stimulating commercialization of technologies developed at Texas institutions	**$16,154,562**
NA	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	**NA**
1	Providing appropriate return on taxpayer investment	**$16,154,562**

Mechanism of Support and Product Development Research Objectives

Applications submitted in the 22.2 review cycle responded to one of three product development research RFAs.

- *Texas Company Product Development Research Award* (TXCO)

  This award mechanism seeks to support early stage "startup" and established companies in the development of innovative products and services with significant potential impact on cancer patient care. The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust

biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Companies must headquarter in Texas.

Strong candidates for the TXCO award have developed a sufficiently robust data package, value proposition, regulatory strategy, manufacturing plan, and experienced business/management team to warrant the amount of funding requested.

Award: Maximum amount $20 million over 36 months

- *Relocation Company Product Development Research Award* (RELCO)

This award mechanism seeks to support early stage "startup" and established companies in the development of innovative products and services with significant potential impact on cancer patient care. The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Companies must relocate to Texas upon receipt of award.

Strong candidates for the RELCO award have developed a sufficiently robust data package, value proposition, regulatory strategy, manufacturing plan, and experienced business/management team to warrant the amount of funding requested.

Award: Maximum amount $20 million over 36 months

- *Seed Award for Product Development Research* (SEED)

This award mechanism seeks to support early stage "startup" companies in the development of innovative products and services with significant potential impact on cancer patient care.

The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Company applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award

Strong candidates for the SEED award have developed compelling discovery stage data and/or developed a working prototype (if applicable) around a novel compound, diagnostic, device, computational tool, etc. that warrants further development efforts to establish proof of concept (POC) on the early pathway to commercial product. In addition, strong candidates have at a minimum developed a strong value proposition, preliminary regulatory strategy, preliminary manufacturing plan, and early business/management team to warrant the amount of funding requested.

Award: Maximum amount of $3 million over 36 months.

CPRIT Award Contract and Risk Mitigation

Investing in early-stage translational cancer research is inherently risky. Products in development at CPRIT Product Development Research awardees that show promise in the laboratory and in animal studies 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 technical failure, human studies are more complex and expensive than laboratory and animal studies.

CPRIT addresses the risk associated with product development research awards by tying disbursement of funds to the grantee achieving specific project goals and objectives. The award 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 Award Recommended by the PDRC for September 2022

ImmuneSensor Therapeutics, Inc. Proposed TXCO Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a TXCO Award for Product Development Research to ImmuneSensor Therapeutics, Inc. for $16,154,562.

ImmuneSensor Therapeutics Inc. is a Dallas-based clinical stage biotechnology company founded on Dr. Zhijian Chen's CPRIT funded research at University of Texas Southwestern. The company is developing a new class of drug called STING agonist that activates the patient's immune system to fight cancers. ImmuneSensor's lead STING agonist, IMSA101 has shown in Phase 1 trial an excellent clinical safety profile and encouraging immune stimulatory activity. ImmuneSensor is proposing a Phase 2 program to evaluate adding IMSA101 to an existing therapy in metastatic solid tumor cancer.

CPRIT Product Development Research Priorities Addressed

ImmuneSensor's proposed project addresses five of the six Product Development Research 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

The pivotal roles of the cGAS-STING pathway and the potential of STING agonists in immuno-oncology are widely recognized. IMSA101 is a STING agonist that showed strong STING-dependent anti-tumor effects in multiple syngeneic mouse tumor models with single-agent treatment either completely reversing tumor growth, or greatly reducing tumor growth rate, leading to cure or extending survival. Such effects were further enhanced when combining with immune checkpoint inhibitors (ICI). The IMSA101 P2 program proposes to evaluate the combination of IMSA101 to ICI-RT regimen for
the treatment of metastatic diseases. The goal is to confirm the IMSA101-ICI-RT triplet as a P3 development and NDA approval pathway. The IMSA101-ICI-RT triplet could generate a greater immune response compared to the ICI-RT doublet, resulting in greater disease control, delay in disease progression leading to improvement in survival.

ImmuneSensor will initiate two phase 2 clinical trials. The first trial is the evaluation of PULSAR plus PD(L)-1 targeting immunotherapy with or without IMSA101 in solid tumor malignancies patients with oligoprogressive disease (OPD). The second trial is the evaluation of PULSAR plus PD(L)-1 targeting immunotherapy with or without IMSA101 in NSCLC and RCC patients with oligometastatic diseases (OMD). Initiation of the trials will be exemplified by completion of study start up and first patient dosed in each trial.

Select Reviewer Comments

"*There is previous CPRIT funding to Dr Chen supporting research in cGAS-STING pathway. There are leaders with diverse experience in drug discovery, clinical development, corporate/business development and expertise in cGAS-STING pathway."*

"*The application is generally well organized, and the team represents relevant operational experience required to execute on the proposed plan. A number of risks and challenges, along with mitigation strategies, are adequately presented."*

"This is a strong application from a team that has completed a first-in-human phase 1 trial of a STING agonist and is moving toward a phase 2 trial. Despite the challenges of the unique trial designs and enrollment criteria, it is a well-thought-out strategy and solid business plan for an exciting new class of IO agents."

September 1, 2022

Dr. Mahendra Patel
CPRIT Oversight Committee Chair
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
CPRIT Program Integration Committee Chair
Via email to wroberts@cprit.texas.gov

Dr. Patel and Mr. Roberts,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research program. The PDRC convened via email on September 1, 2022, and recommends that the Program Integration Committee and the Oversight Committee approves a Product Development Research grant award for ImmuneSensor Therapeutics, Inc. This application was part of the application reviewed during the second cycle of the FY 2022 review process. During due diligence review the PDRC required clarification on key points, which the company updated satisfactorily.

The PDRC did not make any changes to timelines or budgets for the award being recommended for funding. However there is a contingency associated with intellectual property (IP) ownership, which CPRIT should address with the company during contract negotiations.

The one company included in the PDRC's recommendation reflects 50+ hours of individual review panel discussion of the applicant's proposals as well as the PDRC's review of the due diligence report. Our recommendation is 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.

Sincerely,

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

FY22.2 Product Development Review Council Recommendations

Recommendation	ID	Mechanism	Type	PI Last Name	Organization	Application Title	Score from Peer Review	Budget
Recommended to PIC/OC	DP220030	TXCO Therapeutics	New	Sun, L.	ImmuneSensor Therapeutics Inc.	Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of IMSA101 in Combination With Radiotherapy and Checkpoint Inhibitors in Solid Tumor Malignancies	3.5	$16,154,562

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

September 7, 2022

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 a grant contract for the one company that the Oversight Committee will consider for a product development grant award at its September 14, 2022, meeting. The Program Integration Committee has recommended the company for a grant award.

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, § 4.02(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 project proposed for a grant award involves preclinical work and/or 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 the project to begin work as quickly as possible.

Sincerely,

Wayne Roberts
CPRIT Chief Executive Officer

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

September 6, 2022

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 26 grant applications totaling $52,923,076. The PIC recommendations for one product development research grant and 25 academic research grant awards are attached.

Dr. Michelle Le Beau, CPRIT's Chief Scientific Officer and Dr. Ken Smith, CPRIT's Chief Product Development Officer, have prepared overviews of the academic research 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 the information considered by each Review Council 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 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 September 14, 2022. 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 and Dr. Le Beau, and Dr. Smith 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 GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of 25 academic research grant proposals totaling $34,768,514. The recommended grant proposals were submitted in response to the following grant mechanisms: *Core Facility Support Awards (CFSA); Clinical Trials Network Award (CTNA); Early Clinical Investigator Award (ECI); High-Impact/High-Risk Research Awards (HIHRRA)*; and *Recruitment of First-Time, Tenure-Track Faculty Members (RFT).* The Scientific Review Council (SRC) provided the prioritized list of recommendations for the awards to the presiding officers on September 1. The PIC approved the award recommendations as presented by the SRC.

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:

Priority	CFSA	CTNA	ECI	HIHRRA	RFT
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;	✓		✓	✓	✓
Are interdisciplinary or interinstitutional			✓	✓	
Address federal or other major research sponsors' priorities in emerging scientific or institutions of higher education;	✓			✓	
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; and	✓	✓	✓	✓	✓
address the goals of the Texas Cancer Plan.	✓	✓	✓	✓	✓

Academic Research Grant Award Recommendations							
Rank	**ID**	**Mech.**	**Application Title**	**PI**	**PI Organization**	**Budget**	**Final Score**
1	RP220582	CFSA	Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UTSouthwestern Medical Center	Rosen, Michael	The University of Texas Southwestern Medical Center	$4,000,000	1.0
2	RP220646	CFSA	Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas	Lewis, Michael	Baylor College of Medicine	$3,999,996	1.8
3	RP220544	ECI	CPRIT Early Clinical Investigator Award-Christopher Alvarez-Breckenridge	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,500,000	1.8
4	RP220606	HIHRRA	Developing a Novel Optogenetic Recombinase System to Study and Target Metastatic Cancer	Maddipati, Ravikanth	The University of Texas Southwestern Medical Center	$250,000	1.9
5	RP220662	CFSA	UTHSCSA Cancer Genome Sequencing and Computation Core	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$3,998,688	1.9
6	RP220650	HIHRRA	Targeting Nitric Oxide Synthase (NOS) Pathway to Remodel Obesity-Induced Tumor Inflammation in Patients With TNBC	Chang, Jenny	The Methodist Hospital Research Institute	$250,000	1.9
7	RP220631	CFSA	West Texas Pharmacology Core	Kang, Min	Texas Tech University Health Sciences Center	$3,369,480	1.9
8	RP220542	CTNA	Establish the Accelerating Clinical Oncology	Beg, Muhammad	The University of Texas	$3,000,000	1.9

Academic Research Grant Award Recommendations							
Rank	**ID**	**Mech.**	**Application Title**	**PI**	**PI Organization**	**Budget**	**Final Score**
			Research Network-Texas (ACORN-TX) to Enhance Clinical Trial Access in North and Central Texas		Southwestern Medical Center		
9	RP220626	HIHRRA	A Glia-to-Neuron Conversion for Treating Oral Cancer Pain	Tao, Feng	Texas A&M University System Health Science Center	$237,500	2.0
10	RP220558	HIHRRA	Novel Covalent Drugs for BCL6	Fast, Walter	The University of Texas at Austin	$249,999	2.0
11	RP220614	HIHRRA	Understanding the Impact of Immunity on Premalignant Somatic Mosaicism and Cancer Prevention	Zhu, Hao	The University of Texas Southwestern Medical Center	$237,501	2.0
12	RP220666	HIHRRA	Targeting Tumors and the Tumor Microenvironment With Banana Lectin-Expressing T Cells	McKenna, Katie	Baylor College of Medicine	$250,000	2.0
13	RP220567	HIHRRA	Fasting-Induced Microbiome Changes and Radioprotection	Piwnica-Worms, Helen	The University of Texas M. D. Anderson Cancer Center	$249,999	2.0
14	RP220645	HIHRRA	Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy	Alexandrakis, Georgios	The University of Texas at Arlington	$250,000	2.0
15	RP220581	ECI	Hyperspectral, Quantitative Intraoperative Fluorescence Image-Guided Brain Surgery	Urban, Randall	The University of Texas Medical Branch at Galveston	$1,494,784	2.1
16	RP220599	CFSA	Texas Pediatric Cancer Testing (TPCT) Core	Houghton, Peter	The University of Texas Health Science Center at San Antonio	$3,935,480	2.3

Academic Research Grant Award Recommendations							
Rank	**ID**	**Mech.**	**Application Title**	**PI**	**PI Organization**	**Budget**	**Final Score**
17	RP220653	HIHRRA	Novel Modulators of Genomic Instability in Human Cells	Vasquez, Karen	The University of Texas at Austin	$249,932	2.3
18	RP220587	CFSA	Advanced Protein Therapeutics Core	Maynard, Jennifer	The University of Texas at Austin	$3,995,180	2.3
19	RP220592	HIHRRA	Restoration of Phagocytosis Function of Glioma-Associated Microglia/Macrophage by Activating QKI-PPARb-RXRa	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	$250,000	2.4
20	RP220600	HIHRRA	In Vivo Akt Analysis via Chemical Genetics and Nanoparticle-Mediated Probe Delivery	Wang, Degeng	Texas Tech University	$249,999	2.4
21	RP220610	HIHRRA	Identification of Enhancers of T-Cell Antitumor Activity in PDAC Using CRISPR Activation Screening	Maitra, Anirban	The University of Texas M. D. Anderson Cancer Center	$250,000	2.8
22	RP220553	HIHRRA	Reversing Aging-Associated Resistance to Cancer Immunotherapy	Jiang, Wen	The University of Texas M. D. Anderson Cancer Center	$249,976	2.9
23	RP220639	HIHRRA	Targeting NHE6 to Improve Clinical Efficacy of Daratumumab in Myeloma	Yang, Jing	The Methodist Hospital Research Institute	$250,000	2.9

CFSA: Core Facility Support Awards
CTNA: Clinical Trials Network Awards
ECI: Early Clinical Investigator Awards
HIHRA: High-Impact/High Risk Awards

Academic Research Recruitment Grant Award Recommendations *Recruitment of Fist-Time, Tenure-Track Faculty Members*					
Rank	**Application ID**	**Candidate**	**Organization**	**Budget**	**Final Overall Score**
1	RR220097	Jennifer Kong, Ph.D.	The University of Texas at Austin	$2,000,000	1.6
2	RR220092	Emma Chory, Ph.D.	Rice University	$2,000,000	2.0

PRODUCT DEVELOPMENT RESEARCH GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of one product development research grant proposal totaling $16,154,562. The recommended grant proposal was submitted in response to the *Texas Company Product Development Awards* grant mechanism. The Product Development Review Council (PDRC) provided the prioritized list of the recommendation for the award to the presiding officers on September 1, 2022. The PIC approved the award recommendation 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 this product development research proposal 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;
- 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;
- expedite innovations 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.

Product Development Research Grant Award Recommendations ***Texas Company Product Development Awards***						
Rank	**Application ID**	**Applicant Company**	**PI**	**Project Title**	**Budget**	**Final Score**
1	DP220030	ImmuneSensor Therapeutics, Inc.	Sun, Lijun	Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of IMSA101 in Combination With Radiotherapy and Checkpoint Inhibitors in Solid Tumor Malignancies	$16,154,562	3.5

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE CERTIFICATION – SEPTEMBER 2022 AWARDS
DATE:	SEPTEMBER 8, 2022

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 First-Time, Tenure-Track Faculty Members
- Core Facility Support Awards
- Clinical Trials Network Awards
- Early Clinical Investigator Awards
- High-Impact/High-Risk Research Awards
- Texas Company Product Development Research Awards

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.

The PIC's September 6, 2022, recommendation includes three applications that the respective review councils took no action on prior to September 1, 2022. These include two Recruitment of First-Time, Tenure-Track Faculty Member applications from cycle 22.10 and one Texas Company Product Development Research Award from cycle 22.2. While the Scientific Review Council met on August 1 and the product Development Review Council met on July 19 to recommend other applications from each of these mechanisms, both review councils took no action on the three applications noted

here. Because of this, I certified cycle 22.10 Recruitment of First-Time, Tenure-Track Faculty Members and cycle 22.2 Texas Company Product Development Research Awards mechanisms for the August 17, 2022, Oversight Committee meeting. The certification information from pre-receipt through peer review remains the same; therefore, I will not repeat the certifications here but instead will make available copies of the August 2022 certifications. Within this certification, new information regarding the recruitment and Product Development recommendations begins at the programmatic review section that starts on page 4.

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. 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:

In response to the academic, non-recruitment RFAs for Cycle 22.2, CPRIT received 120 applications.

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.

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:

Academic research applications (non-recruitment) are reviewed by peer review panels and recommended to the SRC. 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 six SRC members that attended the Scientific Review Council meeting on July 14, 2022 and the seven SRC members that attended the SRC meeting on September 1, 2022.

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 Product Development Research 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.

Academic Research:

The SRC met on September 1, 2022, to consider 29 non-recruitment applications recommended by the peer review panels following their meetings held on April 26-29, 2022, and May 5, 2022. After review of these applications, the SRC recommended 23 applications to the Program Integration Committee (PIC) for consideration. The SRC also recommended two recruitment cycle 22.10 applications that it took no action on prior to September 1.

Product Development Research:

On September 1, 2022, the Product Development Review Council (PDRC) recommended DP220030 which was reviewed during cycle 22.2. The PDRC began review of this application in FY22; however, they did not reach a final decision on this application and it was left pending at its August 30, 2022, meeting.

DP220030 has a less favorable score than one other application that the PDRC did not recommend within this mechanism. 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.

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 September 6, 2022, PIC meeting as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules. All five PIC members were present for the meeting.

The PIC considered 26 applications and voted to recommend all 26 applications 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.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE CERTIFICATION – AUGUST 2022 AWARDS
DATE:	AUGUST 8, 2022

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 following mechanisms:

- Recruitment of Established Investigators
- Recruitment of First-Time, Tenure-Track Faculty Members
- Texas Company Product Development Awards
- Company Relocation Product Development Awards
- Seed Awards for Product Development Research
- Evidence-Based Cancer Prevention Services
- Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

The following mechanism also received applications during this award cycle; however, did not result in recommendations to the Oversight Committee for its August 17, 2022, meeting: Tobacco Control and Lung Cancer Screening. 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.

At its August 3, 2022, meeting, the PIC voted to recommend an application from Recruitment cycle 22.8 that the PIC previously deferred at its March 4, 2021, meeting. I certified the Recruitment of Established

Investigators mechanism for the May 18, 2022, Oversight Committee meeting; therefore, I will not repeat the certification here but instead will make available copies of those previous certifications.

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. 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:

All Academic Research RFAs were uploaded to the Texas.gov eGrants website. For Recruitment Cycle 22.10, two applications were received for the Recruitment of Established Investigators RFA and 10 applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA.

All applications were submitted through CARS.

Product Development Research:

All Product Development Research RFAs were uploaded to the Texas.gov eGrants Website. For Cycle 22.2, 10 applications were received for the Texas Company Product Development Awards RFA, eight applications were received for the Company Relocation Product Development Research Awards RFA, and 16 applications were received for the Seed Awards for Product Development Research RFA.

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.

Prevention:

For Prevention Cycle 22.2, CPRIT uploaded the RFAs on the Texas.gov eGrants website. For Cycle 22.2, nine applications were received for the Evidence-Based Cancer Prevention Services RFA; three applications were received for the Tobacco Control and Lung Cancer Screening RFA; four applications were received for the Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations RFA.

All applications were submitted through CARS.

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:

One recruitment was voluntarily withdrawn by the applicant after the SRC, but before the Program Integration Committee (PIC) meeting.

Product Development Research:

No applications were withdrawn during this cycle.

Prevention:

One application was 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. No conflicts of interest were declared by the SRC for Recruitment Cycle 22.10.

I reviewed and confirmed that the post review conflict of interest statements were signed by the six SRC members and two ad hoc reviewers that attended the 22.10 Recruitment Review Panel meeting on May 12, 2022, and the six SRC members that attended the Scientific Review Council meeting on July 14, 2022.

<u>Product Development Research</u>:

Product Development Research awards go through a peer review teleconference screening call to determine which applications will be invited to in-person (or video teleconference) 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 business operations and management due diligence review and intellectual property review. ICON, a third party contractor for CPRIT, conducts the business and operations due review while intellectual property review is conducted by CPRIT's Chief Due Diligence and Patent Officer, or outside counsel. However, CPRIT's Chief Strategic Initiatives and Intellectual Property Officer, Tracey Davies, performed the intellectual property due diligence review for DP220053. Dr. Ken Smith was unable to conduct due diligence review because he is CPRIT's Chief Product Development Officer and a voting member of the PIC. Ms. Davies previously performed due diligence for CPRIT as outside counsel and reported no conflict of interest with this application. She does not vote or otherwise take any role in recommending awards to the Oversight Committee. Outside counsel performed IP due diligence review for the remaining product development applications.

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 nine PDRC members that attended the Due Diligence meeting on July 19, 2022.

<u>Prevention</u>:

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 11 peer review members for Prevention Panel 1 on April 25, 2022 and the three PRC members that attended the PRC Programmatic Review meeting on June 3, 2022.

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, Product Development 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>:

The SRC met on May 12, 2022, July 14, 2022, and August 1, 2022, to review the applications submitted for Cycle 22.10 under the Recruitment of Established Investigator, and Recruitment of First-Time, Tenure Track Faculty Members RFAs.

The SRC Chairman provided recommendation letters to the PIC and Oversight Committee Chairmen on July 20 and August 2, 2022. The July 20 letter recommended RR220094, and the August 2 letter included an additional application, RR220101, for the PIC to consider. Prior to the August 2 letter, the SRC favorably reviewed but took no action on RR220101 because of insufficient agency funds.

However, on August 1 additional funds became available enabling the SRC to recommend RR220101 to the PIC and Oversight Committee. The SRC did not make a final decision on four applications submitted during this review cycle.

Product Development Research:

For Cycle 22.2, eleven applications went through due diligence. The Product Development Review Council (PDRC) met on July 19, 2022, and after review and discussion recommended nine applications to the PIC for consideration.

The PDRC's final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. 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 after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

Prevention:

The Prevention Review Council (PRC) met on June 3, 2022, to consider nine applications recommended by the peer review panel following their meeting held on April 25, 2022. After review and discussion of these applications, the PRC recommended all nine applications to the Program Integration Committee (PIC) for consideration. One of the recommended applications was submitted during cycle 22.1 and reviewed earlier in the fiscal year, but the PRC took no action on the application at that time before recommending it to the PIC on June 13, 2022.

I note that on September 10, 2021, Mr. Roberts granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating with grant applicants, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet for each of the prevention mechanisms recommended by the PIC.

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 August 3, 2022, PIC meeting as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules. All five PIC members were present for the meeting; however, Dr. Michelle Le Beau dropped off the video conference call early and did not vote

on the Product Development Research and Prevention award slates. No PIC member reported a conflict of interest with any of the grant application recommendations.

The PIC considered 21 applications that were recommended by the three review councils, including one application that the PIC deferred at its May 4, 2022, meeting. The PIC voted to recommend all 21 applications 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.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Texas Company Product Development Awards

Updated for September 14, 2022, Oversight Committee meeeting

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA C-22.2-TXCO

Texas Company Product Development Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on December 1, 2021

Application Receipt Opening Date: December 1, 2021

Application Receipt Closing Date: January 26, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

Rev 11/3/2021 RFA release

1. KEY POINTS

This Texas Company Product Development Research Award mechanism is governed by the following guidelines:

- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Products must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- 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 Texas based (see section 8.1) and must have a chief executive officer (CEO) as part of the applicant's management team prior to submitting an application. 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. 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.
- For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company. More details on the matching funds requirements are provided below.
    - A grantee approved for 1 or more product development grants that together total a commitment of $20 million or less must dedicate to each grant project $1 of their own funds for every $2 of CPRIT grant award funds.
    - A grantee approved for a product development grant award that causes the total amount of committed CPRIT product development grant award funds to exceed $20 million must increase their matching fund obligation to $1 for every $1

contributed by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under the matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.

  - A company approved for a grant award that would result in more than $30 million in CPRIT product development grant funds must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

- 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. The contract-specific milestones are the Goals & Objectives submitted by the applicant within the proposal. The progress-based release of funds will be dependent on the completion of the applicant's proposed Goals & Objectives for each project year.
- 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 December 4, 2019, may be submitted as a new application, even if it was previously resubmitted (see section 8.2).
- Applicant companies are limited to 1 submission per cycle across all CPRIT Product Development award mechanisms.

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to $6 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. CPRIT has established overarching principles, and each of CPRIT's 3 grantmaking programs (Academic Research, Prevention, and Product Development Research) have established program-specific priorities. Additional priorities focused at the intersection of the 3 programs have also been established and outlined below. The Product Development Research Program's principles and priorities 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 RFAs.

CPRIT's Established Principles:

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

CPRIT's Academic Research, Prevention, and Product Development Research Cross-Program Priorities:

- Prevention and early detection initiatives
- Translation of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

CPRIT's Product Development Research Priorities:

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://priorities.cprit.texas.gov/.

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 accelerating the development of groundbreaking therapeutics, diagnostics, and tools 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://priorities.cprit.texas.gov/.

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) acquisition and 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. 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.

For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company.

A grantee approved for 1 or more product development grants that together total a commitment of $20 million or less must dedicate to each grant project $1 of their own funds for every $2 of CPRIT grant award funds.

A grantee approved for a product development grant award that causes the total amount of committed CPRIT product development grant award funds to exceed $20 million must increase their matching fund obligation to $1 for every $1 contributed by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under the matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.

A company approved for a grant award that would result in more than $30 million in CPRIT product development grant funds must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

7. KEY DATES

RFA release	November 3, 2021
Online application opens	December 1, 2021, 7 AM central time
Applications due	January 26, 2022, 4 PM central time
Invitations to present sent	March 2022
Notifications sent if not invited	March 2022
Presentations to CPRIT*	April 2022
Award Notification	August 2022
Anticipated Start Date	September 2022

***** 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

- Either for-profit or nonprofit companies may apply. However, nonprofit companies must intend to bring a product to market. Applications may be submitted prior to company formation, but company formation must be completed before award receipt. Applicants will be required to provide a data universal numbering system (DUNS) number before award receipt.
- Award recipients 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.

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, the company must fulfill all location requirements identified in the application 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.
- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Project must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- An application last submitted before December 4, 2019, may be submitted as a new application, even if it was previously resubmitted.
- CPRIT is releasing 3 Product Development RFAs in this funding cycle. Please note that in any given application round, applicants are allowed to apply for only 1 Product Development Award (TXCO, RELCO, or SEED). 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.
- An 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.

- An 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 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 applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the 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 December 4, 2019) but not funded may be resubmitted once and must follow all resubmission guidelines. **An application that was last submitted before December 4, 2019, may be submitted as a new application, even if the most recent submittal (prior to December 4, 2019), was a resubmission.** For additional clarity regarding the 22.2 application cycle, this means that an application that was last submitted during or before the 20.1 cycle is considered a new application. In contrast, an application that was last

submitted during or after the 20.2 cycle is considered 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 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. Please note that CPRIT may request to review any correspondence that an applicant has conducted with regulatory agencies (eg, the FDA) as part of the diligence process. 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 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.

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 program.

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
- Unmet Medical Need
- Product Validation/Proof of Concept
- Safety
- Preclinical Strength/Development to Date

- Development Plan
- Competitive Landscape
- Intellectual Property
- Business/Commercial Aspects
- Management and Staffing
- Production/Manufacturing Plan
- Overview of Clinical/Regulatory Plan

More details regarding these topics can be found in the appendices to this document.

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

Please see appendices for more details.

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 December 1, 2021. 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 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 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 usernames. Applications will be accepted beginning at 7 AM central time on December 1, 2021 and must be submitted by 4 PM central time on January 26, 2022. **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 and are intended to allow an applicant to complete and submit an incomplete application that has already been started in CARS. If a request for extension is approved, then CARS will be reopened for an additional 2 hours to allow an applicant with an unsubmitted application to complete and submit it. Applicants are also urged to initiate the registration process on CARS a minimum of 5 business days prior to deadline to ensure enough time to complete and submit an application.

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 as described below.

Checks may be mailed via the US Postal Service to the following address:

Cancer Prevention and Research Institute of Texas
PO Box 12097
Austin, Texas 78711

Contact name: Michelle Huddleston
Phone 1-512-305-8420

Mail sent via a delivery services (ie, FedEx, UPS, etc) will need to use this address:

Cancer Prevention and Research Institute of Texas
Wm B 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. Please do not submit letters of support as part of your application package. **Any such information will be removed from your application before review**.

10.4.1. 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.

10.4.2. Layperson's Summary (1,500-character maximum)

Provide a summary of the proposed project using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Describe the overall goals of the project, 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.

10.4.3. 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.

10.4.4. 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.

10.4.5. 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-oriented page. The slides should succinctly capture all essential elements of the application and should stand alone.

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 December 4, 2019, 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 **product profile (PP)**. The format for the PP should be a target product profile (TPP) in the case of a therapeutic, or analogous document for a medical device, in vitro diagnostic, or service that projects a clear path to full commercialization. The PP 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 PP 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 PP will be known at the time of application. Consequently, not only does the PP 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 PP 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 https://www.ich.org/page/ctd) for 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 a 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 (such as the company's interactions with regulatory agencies like the FDA, etc) to support the application may 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 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 and MUST be used when completing your application. 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. <u>Please avoid redundancy</u>. Note that the section "Funding to Date" above may exceed this 1-page limit <u>if necessary</u>.

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 either the provided "Product Development Research Programs: Biographical Sketch" template or the NIH biographical sketch format. (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 2022 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 2022 is from September 1, 2021, through August 31, 2022. 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. If funding is requested for a role that is not currently occupied, applicant should note "new hire" as name.

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, Contractual (Subaward/Services Contracts), 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. Use of the provided Budget Justification template is mandatory. 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 utilizes 2 methods of disbursement of grant funds, (1) reimbursement and (2) advancement. Under the reimbursement method, the grantee is expected to finance its operations with its own working capital. Under the advancement method, CPRIT disburses grant funds in advance of the grantee incurring expenses. Grantees must be approved by the Oversight Committee to receive advancement of funds. Please see Chapter 8 of the CPRIT Grant Policies & Procedures Guide for additional details regarding the disbursement of grant funds.

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. For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company. See section 6 ("Funding Information") of the RFA for more details.

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—international applicants should use the email address below)
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: Pharmacodynamic Proof of Concept

- Considering in vivo preclinical pharmacodynamic 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 pharmacodynamic 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)

Unmet Medical Need

- Assuming successful accomplishment of development objectives, 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?

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/Regulatory Aspects

- 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 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 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?

Business/Commercial Aspects

- 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)
22.2 Product Development Research Panel 1
(22.2_PDR_PDP_1)
Observation Report

Report No.	2022-03-21 22.2_PDR_PDP_1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel 1 (22.2 _PDR_PDP_1)
Panel Date:	March 21, 2022
Report Date:	March 29, 2022

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 22.2 Product Development Research Panel 1 (22.2_PDR_PDP_1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on March 21, 2022.

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: Ten (10) applications were discussed and six (6) applications were not discussed
- Panelists: One (1) panel chair, four (4) PDRC members, eight (8) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Four (4)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The applications for which there were COIs were not discussed.

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.

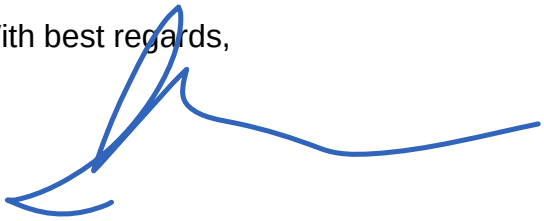
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel_2
(22.2_PRD_PDP_2)
Observation Report

Report No.	2022-03-22 22.2_PRD_PDP_2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel_2 (22.2 _PRD_PDP_2)
Panel Date:	March 22, 2022
Report Date:	March 29, 2022

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 22.2 Product Development Research Panel_2 (22.2_PRD_PDP_2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on March 22, 2022.

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: Thirteen (13) applications were discussed and five (5) applications were not discussed
- Panelists: One (1) panel chair, three (3) PDRC members, nine (9) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- 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) Conflicts of Interest (COIs) identified prior to and/or during the meeting. There were two (2) COIs on the application discussed and five (5) COIs on the applications not discussed. Those with 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.

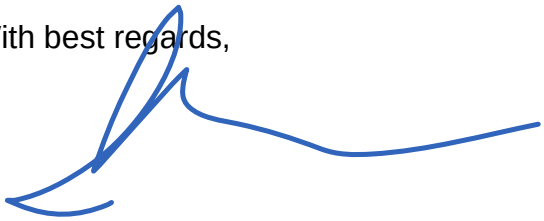
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel-1 (22.2 PDR-PDP1)
Observation Report

Report No.	2022-04-11 22.2_PDR-PDP1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel-1 (22.2 _PDR-PDP1)
Panel Date:	April 11, 2022 and April 12, 2022
Report Date:	June 8, 2022

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 22.2 Product Development Research Panel-1 (22.2_PDR-PDP1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on April 11, 2022 and April 12, 2022.

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 nine (9) applications were not discussed
- Panelists : One (1) panel chair, four (4) PDRC members eight (8) expert reviewers, and two (2) advocate reviewers were present on both days
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) on day 1 and six (6) on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2) were present on both days
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

In total there were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meetings over two days. COI(s) 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. Our observations are limited to the information made available.

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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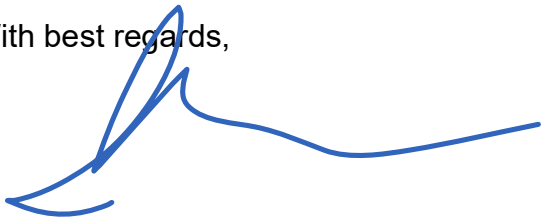

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel-2 (22.2 PDR-PDP2)
Observation Report

Report No.	2022-04-13 22.2_PDR-PDP2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel-2 (22.2 _PDR-PDP2)
Panel Date:	April 13, 2022 and April 14, 2022
Report Date:	June 8, 2022

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 22.2 Product Development Research Panel-2 (22.2_PDR-PDP2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on April 13, 2022 and April 14, 2022.

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: Eight (8) applications were discussed and ten (10) applications were not discussed
- Panelists: One (1) panel chair, three (3) PDRC members, ten (10) expert reviewers, and two (2) advocate reviewers on both days
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Seven (7) on day 1 and five (5) on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2) on both days
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) Conflicts of Interest (COIs) identified prior to and/or during the meeting. COI(s) 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. Our observations are limited to the information made available.

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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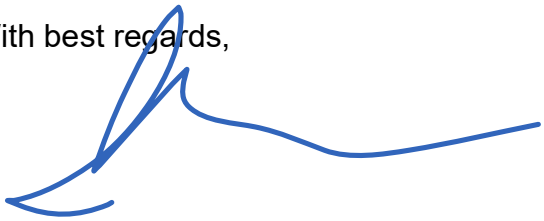

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Senior Partner
Business & Financial Management Solutions, LLC

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Duligence Panel-1 (22.2_PDR_DDP1)
Observation Report

Report No.	2022-07-13 22.2_PDR_DDP1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Duligence Panel-1 (22.2 _PDR_DDP1)
Panel Date:	July 13, 2022
Report Date:	July 20, 2022

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 22.2 Product Development Research Due Duligence Panel-1 (22.2_PDR_DDP1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on July 13, 2022.

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: Five (5) applications were discussed
- Panelists: One (1) panel chair, three (3) expert reviewers, and four (4) PDRC members
- 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
- ICON Due Diligence Evaluators: Five (5)
- ICON Due Diligence Evaluators did only provide input when requested

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Our observations are limited to the information made available.

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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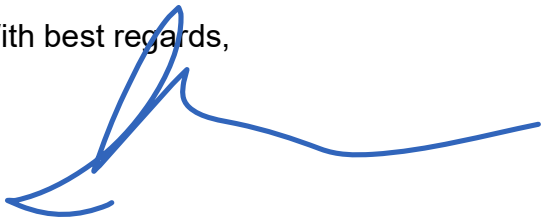

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Duligence Panel-2 (22.2_PDR_DDP2)
Observation Report

Report No.	2022-07-14 22.2_PDR_DDP2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Duligence Panel-2 (22.2 _PDR_DDP2)
Panel Date:	July 14, 2022
Report Date:	July 20, 2022

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 22.2 Product Development Research Due Duligence Panel-2 (22.2_PDR_DDP2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on July 14, 2022.

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: Six (6) applications were discussed
- Panelists: One (1) panel chair, Four (4) expert reviewers, and three (3) PDRC members
- 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: Four (4)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- ICON Due Diligence Evaluators: Three (3)
- ICON Due Diligence Evaluators did only provide input when requested

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Our observations are limited to the information made available.

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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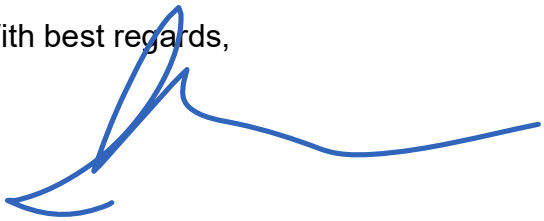

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Diligence Ranking (22.2_PDR_DD Ranking)
Observation Report

Report No.	2022-07-19 22.2_PDR_DD Ranking
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Diligence Ranking (22.2 _PDR_DD Ranking)
Panel Date:	July 19, 2022
Report Date:	July 20, 2022

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 22.2 Product Development Research Due Diligence Ranking (22.2_PDR_DD Ranking) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on July 19, 2022.

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: Ten (10) applications were discussed and one (1) applications were not discussed
- Panelists: One (1) panel chair, one (1) vice chair, and seven (7) PDRC Members
- 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Our observations are limited to the information made available.

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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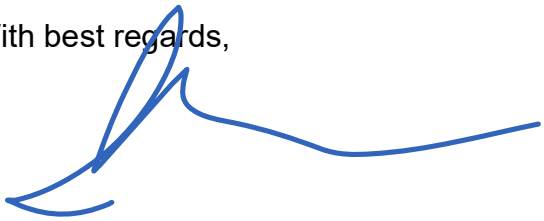

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Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel - Discussion of DP220030 (22.2_PDRC DP220030P1)
Observation Report

Report No.	2022-08-18 22.2_PDRC DP220030P1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel - Discussion of DP220030 (22.2 _PDRC DP220030P1)
Panel Date:	August 18, 2022
Report Date:	August 22, 2022

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 22.2 Product Development Research Panel - Discussion of DP220030 (22.2_PDRC DP220030P1) meeting. The meeting was chaired by D. Shoemaker and conducted via videoconference on August 18, 2022.

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: One (1) applications were discussed
- Panelists: One (1) panel chair, and three (3) 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: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Our observations are limited to the information made available.

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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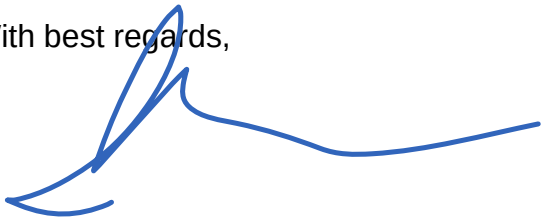
With best regards,



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Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel - Discussion of DP220030 (22.2_PDRC DP220030)
Observation Report

Report No.	2022-08-30 22.2_PDRC DP220030
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel - Discussion of DP220030 (22.2 _PDRC DP220030)
Panel Date:	August 30, 2022
Report Date:	September 2, 2022

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 22.2 Product Development Research Panel - Discussion of DP220030 (22.2_PDRC DP220030) meeting. The meeting was chaired by Jack Geltosky and co-chaired by David Shoemaker conducted via videoconference on August 30, 2022.

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: One (1) applications was discussed
- Panelists: One (1) panel chair, one (1) panel vice 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no (0) Conflicts of Interest (COI) identified prior to and/or during the meeting.

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.

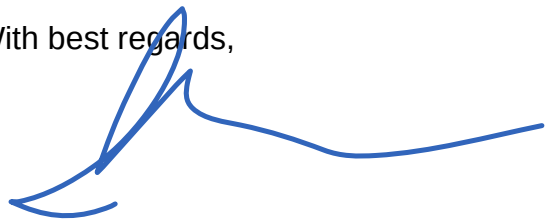
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT) 22.2 Product Development Research Panel - Discussion of DP220030 (22.2 Ad Hoc PDRC DP220030) Observation Report

Report No.	2022-09-01 22.2_Ad Hoc PDRC_DP220030
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel - Discussion of DP220030 (22.2 _Ad Hoc PDRC_DP220030)
Panel Date:	September 1, 2022
Report Date:	September 2, 2022

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 22.2 Product Development Research Panel - Discussion of DP220030 (22.2_Ad Hoc PDRC_DP220030) meeting. The meeting was conducted via email on September 1, 2022, and did not have an assisgned chairperson.

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

Three (3) 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: One (1) applications was discussed
- Panelists: No (0) panel chair, and four (4) 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

Based on COI document from August 30 meeting There was no (0) Conflicts of Interest (COIs) on application DP220030 identified prior to the meeting.

A list of all attendees, a sign-in log and informational materials were not provided by GDIT 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. This report is based on the receivers and respondses to an email correspondes from September 1. All material such as attendees and COI are perceived to be from August 18 2022 meeting.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Product Development Research Cycle 22.2

Awards Announced at the August 17, 2022, and September 14, 2022, Oversight Committee Meetings

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 22.2 include: *Seed Awards for Product Development Research; Company Relocation Product Development Research Awards;* and *Texas Company Product Development Research 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/Principal Investigator	Principal Investigator Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
DP220053	Kingman, Shannon	Rapamycin Holdings Inc.	David Cummings
Applications not considered by the PIC or Oversight Committee:			
DP220058	Vicci Korman	Veravas, Inc.	Steven Weinstein
DP220060	Eric Rothe	Tiburon Bio, Inc.	Elaine Jones
DP220061	Chen Liu	CHEN LIU	Steven Weinstein
DP220042	David Arthur	Salarius Pharmaceuticals, Inc.	Kristine Swiderek
DP220050	Amos Ofer	EnCellX Inc.	Michael Cheng
DP220052	Timothy Coleman	Nemucore Medical Innovations, Inc.	Alan West, Lior Braunstein, Lee Greenberger, Michael Cheng
DP220056	Douglas Baum	QSAM Biosciences Inc.	Roy Cosan

High Level Summary of Due Diligence

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- PLUS Therapeutics for $17,613,605.

The PDRC did not recommended any contract contingencies for this award. The award recommendation to PLUS Therapeutics is contingent on the successful completion of amending the License Agreement between PLUS Therapeutics and NanoTX.

PLUS Therapeutics

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.

Plus Therapeutics is a publicly listed company based in Austin. Plus is developing a Rhenium-186 NanoLiposome (186RNL), which is a novel radiotherapeutic to combat several cancers including recurrent glioblastoma, 186RNL is safe and well-tolerated while delivering a radiation dose to the tumor that is up to 15 times higher than typically achievable with standard radiation therapy. Plus is developing 186RNL to treat leptomeningeal metastases. Leptomeningeal Metastases (LM) are a rare but typically fatal complication of advanced cancer that affects the fluid-lined structures of the central nervous system. LM are diagnosed in 5% of cancer patients.

The investigational product is BMEDA-chelated Rhenium-186 NanoLiposome (186RNL). Rhenium-186 is an ideal radionuclide for CNS cancers such as LM because of its long 90-hour half-life, beta particles' short ~2mm path length, low dose rate, and high radiation density that overwhelms proliferating cellular innate DNA repair mechanisms. For 186RNL treatment of LM in humans, PLUS has obtained FDA Fast Track designation and IND clearance and will pursue FDA Orphan Drug and Breakthrough Therapy designations in the future.

The purpose of the two-part, Texas-based multicenter (The University of Texas Health Science Center San Antonio, The University of Texas Southwestern Medical Center, and The University of Texas MD Anderson Cancer Center) Phase clinical trial is to characterize the safety, tolerability, PK, dosimetry, and antitumor activity of 186RNL administered intrathecally, via an intraventricular catheter system (Ommaya reservoir), as a single agent in 61 LM subjects. If successful, PLUS intends to seek FDA investigational new drug (IND) clearance to initiate and complete a Phase 2 pivotal trial in 120 subjects (final N subject to data and statistical analysis plan) with leptomeningeal metastases to support a new drug application (NDA) submission with the FDA.

The company expects 186RNL to deliver a much higher and more targeted dose of radiation during a single administration compared to traditional RTs; have a high safety margin with minimal risk of bone marrow suppression; may be able to treat all LM patients, unlike some other therapies that rely on tumor targeting technology for a subset of patients; ease of administration with well-accepted and currently utilized access technology.

Plus intends to complete parts 1 and 2 of a Multicenter Phase 1 Clinical Trial of IT-Delivered 186RNL to treat LM, which will include compiling safety data, identifying a maximum tolerated dose, assess the safety, tolerability, efficacy of 186RNL in subjects with LM for Phase 2 pivotal clinical trial. Plus intends to complete Multicenter Phase 2 Clinical Trial of IT-Delivered 186RNL to treat LM, which will lead to preparations for filing an NDA submission to the FDA.

Select Reviewer Comments

"*This tackles the issue of leptomeningeal metastasis with no therapy at the moment. IND has been filed and cleared by the FDA. In spite of some weaknesses about lack of preclinical data particularly in combination therapy for some models, the application remains solid and promising."*

"*The strengths are high unmet need albeit a very small population. Data in GBM are encouraging. There is FDA green light for the next clinical trial. The competition is limited, and the biomarker strategy if executed should improve targeting the most likely to respond..."*

"The intended product is currently already in clinical trials in glioblastoma and overall de-risks the intended product, clinical strategy, and the company."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Atom Mines for $2,500,000.

The PDRC did not recommend any contract contingencies for this award.

Atom Mines

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.

Atom Mines is a small Austin-based company which utilized a Magnetically Activated and Guided Isotope Separation ("MAGIS") technology developed at The University of Texas at Austin, which will enable the production of the stable isotope Ytterbium-176 (176Yb) needed to make the radio-isotope Lutetium-177 (177Lu). 177Lu is an effective beta-therapy agent approved for certain neuroendocrine cancers and soon to be approved for prostate cancer, the second leading cause of cancer death in men, with clinical trials underway for a range of cancers. 177Lu can be used to target small tumors and dispersed, inoperable metastatic cancer using precise delivery molecules. 176Yb is currently only available in small quantities from Russia and that supply is uncertain due to geopolitics and competition for limited production capacity.

Ytterbium-176 (176Yb) is the stable precursor required to make carrier-free 177Lu, and 176Yb is currently only available in very limited quantities from Russia. Russian supplies have remained limited due to competition for production capacity for other isotopes, while global demand has more than doubled. This supply is in jeopardy due to deteriorating geopolitics, corruption, and competition for limited calutron separation capacity.

A reliable, domestic source of pure 176Yb is required to produce sufficient carrier-free 177Lu to support FDA-approved drugs and ongoing cancer research, trials, and therapies in Texas and globally. Novartis has two products Pluvicta and Lutathera which utilize 177Lu. Atom Mines utilizes an isotope separation developed by Prof. Mark G. Raizen at The University of Texas at Austin. Magnetically Activated and Guided Isotope Separation ("MAGIS") uses lasers to temporarily magnetize atoms that is then followed by separation with arrays of magnets.

Atom Mines LLC has fully demonstrated 176Yb enrichment to medical-grade purity of 99.5%. MAGIS will enable domestic commercial production of 176Yb, as well as other rare isotopes for widespread medical use. Atom Mines intends to scaleup 176Yb production initially to 200 grams; validate purity of routine batches and of 177Lu produced by industry partner and

irradiators. Atom plans to scale up to 500 grams within three years and ultimately to kilogram quantities, which will support tens of thousands of doses for prostate cancer therapy per year.

Select Reviewer Comments

"*Indeed, the Department of Energy openly recognizes the lack of separation capabilities in the United States and the need for new domestic capabilities. The company has demonstrated that Novartis has a need for this material to develop and test novel prostate cancer therapy and has a production site in Texas, as well as a global distribution partnership with a German company, Eckert and Ziegler, which has invested in the company."*

"Atom Mines will use the efficiency of MAGIS technology to greatly reduce the cost of separating stable isotopes and make important medical isotopes for therapeutics already approved or in the process of approval."

"There is no risk in this proposal short of not being able to meet the demand at commercial scale since several possible therapeutics may use this radiotherapeutic approach."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Rapamycin Holdings, Inc. for $16,999,999.

The PDRC recommended the following contract contingency for this award. Emtora's relationship with Southwest Research Institute with regard to intellectual property and manufacturing for the new formulation of eRapa should be specified.

Rapamycin Holdings, 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.

Emtora Biosciences (formerly Rapamycin Holdings Inc.) is a San Antonio company that has developed eRapa, a novel form of the FDA-approved active ingredient rapamycin. Rapamycin has previously shown promise in treating gastrointestinal diseases and in cancer prevention, but is limited by toxicity. eRapa is targeted to the colon and is delivered at lower doses, resulting in lower toxicity. The company is developing eRapa to prevent colorectal cancer in patients with Familial Adenomatous Polyposis (FAP). In 2019, Emtora received a CPRIT Product Development (SEED) award for a Phase IIa study of eRapa in FAP, which is currently underway.

Data supports that rapamycin augments the immune system, prevents cancer in cancer-prone animal models, and prolongs health and life span. It has been demonstrated that rapamycin reduces the percentage of CD4 and CD8 T lymphocytes that express PD-1 (exhaustion marker), which inhibits T cell signaling and is more highly expressed with age and exposure to cancer. The results of Emtora's Phase I clinical trials in prostate cancer indicate that e-Rapa is safe and well-tolerated at all doses and schedules tested; more tolerable at intermittent dosing schedules; has no adverse effect on quality of life; has a consistent and predictable absorption profile (unlike rapamycin); produces measurable and favorable changes in the immune system; and no patients on eRapa experienced disease progression during the study.

Emtora proposes to manufacture drug product to support the addition of a fourth cohort in the current Phase IIa study of eRapa in FAP. The proposal would expand and complete the CPRIT-funded Phase IIa study of eRapa in Familial Adenomatous Polyposis (FAP) and prepare for and execute Randomized Placebo-Controlled Trial of eRapa in FAP.

Select Reviewer Comments

“*This new encapsulated rapamycin formulation, eRapa, is targeted specifically to the colon and is delivered at a consistent and lower dosage, not only reducing toxicities but also capitalizing on the potential of partial inhibition of the mechanistic target of rapamycin (mTOR) to act as a chemopreventive agent*.”

“*The applicant has a good standing with CPRIT through a previous Seed Award, has received ODD, has an open IND, and is currently in phase 2a clinical trials in FAP. As such, the proposal is highly de-risked.”*

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- ImmuneSensor Therapeutics Inc. for $16,154,562.

The PDRC did not recommended any contract contingencies for this award. The award recommendation to ImmuneSensor is contingent on having a CPRIT appointed Board Observer.

ImmuneSensor Therapeutics 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.

ImmuneSensor Therapeutics Inc. is a Dallas, Texas-based clinical stage biotechnology company founded on Dr. Zhijian Chen's CPRIT funded research at University of Texas Southwestern. The company is developing a new class of drug called STING agonist that activates the patient's immune system to fight cancers. ImmuneSensor's lead STING agonist, IMSA101 has shown in Phase 1 trial an excellent clinical safety profile and encouraging immune stimulatory activity. ImmuneSensor is proposing a Phase 2 program to evaluate adding IMSA101 to an existing therapy in metastatic solid tumor cancer.

The pivotal roles of the cGAS-STING pathway and the potential of STING agonists in immuno-oncology are widely recognized. IMSA101 is a STING agonist that showed strong STING-dependent anti-tumor effects in multiple syngeneic mouse tumor models with single-agent treatment either completely reversing tumor growth, or greatly reducing tumor growth rate, leading to cure or extending survival. Such effects were further enhanced when combining with immune checkpoint inhibitors (ICI). The IMSA101 P2 program proposes to evaluate the combination of IMSA101 to ICI-RT regimen for the treatment of metastatic diseases. The goal is to confirm the IMSA101-ICI-RT triplet as a P3 development and NDA approval pathway. The IMSA101-ICI-RT triplet could generate a greater immune response compared to the ICI-RT doublet, resulting in greater disease control, delay in disease progression leading to improvement in survival.

ImmuneSensor will initiate two phase 2 clinical trials. The first trial is the evaluation of PULSAR plus PD(L)-1 targeting immunotherapy with or without IMSA101 in solid tumor malignancies patients with oligoprogressive disease (OPD). The second trial is the evaluation of PULSAR plus PD(L)-1 targeting immunotherapy with or without IMSA101 in NSCLC and RCC patients with oligometastatic diseases (OMD). Initiation of the trials will be exemplified by completion of study start up and first patient dosed in each trial.

Select Reviewer Comments

"There is previous CPRIT funding to Dr Chen supporting research in cGAS-STING pathway. There are leaders with diverse experience in drug discovery, clinical development, corporate/business development and expertise in cGAS-STING pathway."

"The application is generally well organized, and the team represents relevant operational experience required to execute on the proposed plan. A number of risks and challenges, along with mitigation strategies, are adequately presented."

"This is a strong application from a team that has completed a first-in-human phase 1 trial of a STING agonist and is moving toward a phase 2 trial. Despite the challenges of the unique trial designs and

De-Identified Overall Evaluation Scores

Texas Company Product Development Awards

Product Development Research Cycle 22.2

On September 1, 2022, the Product Development Review Council (PDRC) recommended DP220030 with a less favorable score than one other application that it did not recommend within this mechanism. 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
DP220055^	2.0
DP220039^	2.2
DP220053^	2.7
a	3.0
DP220030*	3.5
b	4.0
c	4.3
d	4.4
e	5.9

* Recommended for grant award by the PDRC on September 1, and subsequently the PIC on September 6, 2022.
^ Approved for award by the Oversight Committee on August 17, 2022.

Final Overall Evaluation Scores and Rank Order Scores

July 27, 2022

Dr. Mahendra Patel
CPRIT Oversight Committee Chair
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
CPRIT Program Integration Committee Chair
Via email to wroberts@cprit.texas.gov

Dr. Patel and Mr. Roberts,

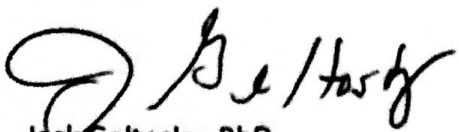
On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 22.2 grant award cycle. The PDRC convened on July 19, 2022, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Atom Mines, InformAI Inc., Xerient Pharma Inc., PLUS Therapeutics, Inc., Stellanova Therapeutics, Asylia Therapeutics, Rapamycin Holdings Inc., NUCORE Medical and PanTher Therapeutics. The attached table reflects the ranked award recommendation for the nine (9) grant applications.

The PDRC did not make any changes to timelines or budgets for the nine (9) projects recommended for funding. However, two (2) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP220053 and DP220054 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP220066 related to clinical data, timelines and development plans. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

I also note that at its July 19, 2022, 22.2 Due Diligence Meeting, the PDRC took "No Action" on one (1) application for CPRIT FY 2022 award budget reasons and to receive additional information. We anticipate that the PDRC will make an award recommendation, if any, regarding this pending application for your consideration as early as the September 2022 Oversight Committee meeting.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review 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.

Sincerely,



Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

FY22.2 Product Development Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Organization	Application Title	Score from Peer Review
1	DP220039	TXCO Therapeutics	Resubmission	Sims, A.	PLUS Therapeutics, Inc.	Single-Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety and Efficacy, Leading to Pivotal Registrational Trial	2.2
2	DP220028	SEED Therapeutics	Resubmission	Schuler, E.	Stellanova Therapeutics, Inc.	Development of DKK3-Targeted Therapeutic Antibodies for Cancer	2.3
3	DP220038	SEED Therapeutics	New	Miller, J.	Asylia Therapeutics	Humanization, Validation, and Clinical Translation of Cell Surface Heat Shock Protein 70-Targeted Antibody-Drug Conjugates for T-Cell Non-Hodgkin Lymphomas	2.3
4	DP220055	TXCO MD&D	New	Dorius, K.	Atom Mines	Commercial-Scale Enrichment of Stable Ytterbium-176 for Production of No-Carrier-Added Lutetium-177 for Use in Prostate Cancer Therapy	2.0
5	DP220053	TXCO Therapeutics	New	Kingman, S.	Rapamycin Holdings Inc.	Development of eRapa for the Treatment of Familial Adenomatous Polyposis, a Rare Genetic Disease Associated With a High Risk of Colorectal Cancer	2.7
6	DP220043	SEED Therapeutics	New	Taniguchi, C.	Xerient Pharma Inc.	Oral Amifostine as an Upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer	2.2
7	DP220063	SEED MD&D	New	Havelka, J.	InformAI Inc.	RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology	2.2
8	DP220066	RELCO Therapeutics	New	Indolfi, L.	PanTher Therapeutics, Inc	Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer	3.6
9	DP220054	SEED MD&D	New	Nathan, J.	NUCORE MEDICAL	Clinical Validation of the MiTR Core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention	3.4

September 1, 2022

Dr. Mahendra Patel
CPRIT Oversight Committee Chair
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
CPRIT Program Integration Committee Chair
Via email to wroberts@cprit.texas.gov

Dr. Patel and Mr. Roberts,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research program. The PDRC convened via email on September 1, 2022, and recommends that the Program Integration Committee and the Oversight Committee approves a Product Development Research grant award for ImmuneSensor Therapeutics, Inc. This application was part of the application reviewed during the second cycle of the FY 2022 review process. During due diligence review the PDRC required clarification on key points, which the company updated satisfactorily.

The PDRC did not make any changes to timelines or budgets for the award being recommended for funding. However there is a contingency associated with intellectual property (IP) ownership, which CPRIT should address with the company during contract negotiations.

The one company included in the PDRC's recommendation reflects 50+ hours of individual review panel discussion of the applicant's proposals as well as the PDRC's review of the due diligence report. Our recommendation is 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.

Sincerely,

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

FY22.2 Product Development Review Council Recommendations

Recommendation	ID	Mechanism	Type	PI Last Name	Organization	Application Title	Score from Peer Review	Budget
Recommended to PIC/OC	DP220030	TXCO Therapeutics	New	Sun, L.	ImmuneSensor Therapeutics Inc.	Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of IMSA101 in Combination With Radiotherapy and Checkpoint Inhibitors in Solid Tumor Malignancies	3.5	$16,154,562

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 10
Recruitment of First-Time, Tenure-Track Faculty Members

Updated for September 14, 2022, Oversight Committee meeting

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-22.1-RFT

Recruitment of First-Time Tenure-Track Faculty Members

Please also refer to the Instructions for Applicants document, which will be posted on June 22, 2021

Application Receipt Dates:

June 22, 2021-June 20, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

TABLE OF CONTENTS

RFA VERSION HISTORY

6/22/21 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 $6 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
- 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
- Increasing the life sciences infrastructure

Priorities Across CPRIT's 3 Programs:

- Prevention and early detection initiatives
- Translational of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science 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
- Expand access to innovative clinical trials

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. Candidates with research programs addressing **CPRIT's priority areas for research are encouraged**. These include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational biology and analytic methods, childhood cancers, hepatocellular cancer, and expansion of access to innovative clinical trials.

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.

Applications nominating individuals who are well prepared to pursue careers in patient-oriented research and who have demonstrated exceptional potential to lead innovative discovery campaigns through conduct of clinical trials are appropriate for this mechanism and encouraged.

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, publications, 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 must 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. 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 and a detailed justification is provided along with an institutional plan should the additional funds not be approved. Scholars may request funds for travel for 2 project staff to attend CPRIT's conference.

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 grant application submissions by Institutions 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, 2022) or in the first quarter of the next fiscal year (starting September 1, 2022).

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. 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 or at another Texas institution.

- *Applications nominating a candidate for a faculty position at the Texas institution where he or she is completing postdoctoral training that do not clearly demonstrate a subsequent career pathway to independence for the candidate will not be looked upon with favor.*
- 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 (which includes the Nominator's credentials and email address) 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 FY22. 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 must 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 following guidelines should be followed when documenting the institutional commitment to the candidate:

- The institutional commitment should be clearly documented 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.
- The institutional commitment letter must include the following statement regarding the institution's financial commitment required to meet the 50% match.
    - This institutional financial commitment will not be offset by funds from a career transition award (K99/R00) or an investigator-initiated award received by the

candidate. If an award dictates that such funds must be used for salary, the corresponding amount of institutional funds committed to pay the candidate's salary will be redirected to allow the candidate to use them for program support.

- Institutional commitment as described above must be presented in a table (example below) that clearly identifies the salary amount, sources of salary, and any additional research support from institutional sources over the course of the CPRIT award. Note that a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the candidate.
- Include a brief job description for the candidate should recruitment be successful.
- Describe the institutional environment and any professional commitments to the candidate including, but not limited to, dedicated personnel, access to students, space assignment, and access to shared equipment, and discuss all other agreements between the institution and the candidate.
- 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 highly 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 its 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 cannot be used to demonstrate an institutional commitment to the candidate.

Example of an acceptable Institutional Commitment table:

Candidate's Name, Institutional Commitments					
	Year 1	Year 2	Year 3	Year 4	Year 5
Salary/Benefits					
Research Support					

Administrative Support					
Moving Expenses					

Total =

Note: CPRIT acknowledges that the institutional commitments by category may change during the course of the award; however, the total financial commitment to the candidate must remain equal to or greater than 50% of the CPRIT award.

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 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 should be included in the Publications/References section (see 8.2.7).**

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 not allowed after the application is submitted to CPRIT."

8.2.7. Publications/References (1 page)

Provide a concise and relevant list of publications/references cited for the application. Any appropriate citation format is acceptable; official journal abbreviations should be used.

8.2.8. 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 highly 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).

8.2.9. 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.

8.2.10. 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.

8.2.11. 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.

8.2.12. 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.

8.2.13. 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.

8.2.14. 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, Texas Administrative Code, Title 25, Chapters 701 to 703.

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, Texas Administrative Code, Title 25, Chapters 701 to 703.

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 22, 2021

Application Receipt and Review Timeline

Application Receipt System opens 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 22, 2021	Continuous – dependent upon available funding	Monthly by the 15th day of the month	June 20, 2022

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 Texas Administrative Code, Title 25, Chapters 701 to 703.

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 Texas Administrative Code, Title 25, Chapters 701 to 703.

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, Texas Administrative Code, Title 25, Chapters 701 to 703.

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. CPRIT requires funding acknowledgement to include the award grant ID on all print and visual materials that are funded in whole or in part by CPRIT grants. Examples of print and visual materials include, but are not limited to, publications, brochures, pamphlets, project websites, videos and media materials. Grantees must have written approval from CPRIT prior to the purchase of any equipment. If the equipment is clearly defined in the grantee's budget submitted with the initiating award requirements, then approval of the grant award constitutes "prior approval" for the purchase. 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, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

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, Texas Administrative Code, Title 25, Chapters 701 to 703, 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.

Email: Research@cprit.texas.gov
Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.10 Academic Research - Recruitment Review Panel
(22.10_SRC_REC)
Observation Report

Report No.	2022-05-12 22.10_SRC_REC
Program Name:	Academic Research
Panel Name:	22.10 Academic Research - Recruitment Review Panel (22.10 _SRC_REC)
Panel Date:	May 12, 2022
Report Date:	May 13, 2022

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 22.10 Academic Research - Recruitment Review Panel (22.10_SRC_REC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on May 12, 2022.

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 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: Twelve (12) applications were discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and two (2) ad-hoc reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- 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 two (2) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The COI was 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.

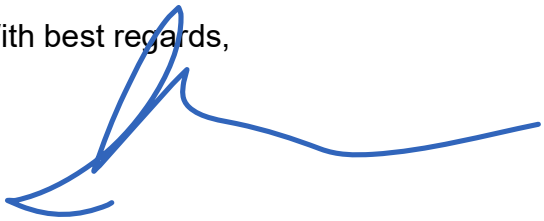
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.10 Academic Research Science Review Council
(22.10_SRC_REC_10)
Observation Report

Report No.	2022-07-14 22.10_SRC_REC_10
Program Name:	Academic Research
Panel Name:	22.10 Academic Research Science Review Council (22.10 _SRC_REC_10)
Panel Date:	July 14, 2022
Report Date:	July 20, 2022

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 22.10 Academic Research Science Review Council (22.10_SRC_REC_10) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on July 14, 2022.

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 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: One (1) application was discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: One (1)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT by request an hour before the meeting to aid in the observation of the objectives. COI document was not provided until the day after the meeting. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

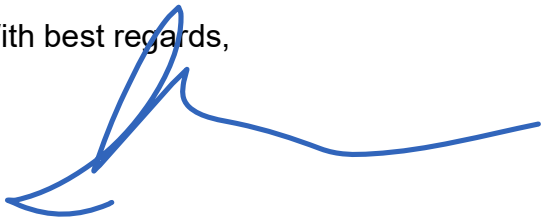
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.10 Academic Research Review Panel (22.10 Ad Hoc SRC REC)
Observation Report

Report No.	2022-08-01 22.10_Ad Hoc SRC_REC
Program Name:	Academic Research
Panel Name:	22.10 Academic Research Review Panel (22.10 _Ad Hoc SRC_REC)
Panel Date:	August 1, 2022
Report Date:	August 3, 2022

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 22.10 Academic Research Review Panel (22.10_Ad Hoc SRC_REC) meeting. The meeting was conducted via email on August 1, 2022, and did not have an assisgned chairperson.

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

Three (3) 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: One (1) application was discussed
- Panelists: No (0) panel chair, and seven (7) reviewers
- Panelists' discussions were limited to the application approval
- GDIT staff employees: One (1)
- GDIT staff did not participate in emails concerning the merits of applications emails for which BFS was included on the response
- CPRIT staff employees: Two (2)
- CPRIT program staff did not respond to emails for which BFS was included on the response

Per CPRIT Academic Cancer Research and Reccuirtment Review Panel policy, Conflicts of Interest (COIs) are not excluded from the setting of cutoffs for funding recommendations since there is no scoring or actual discussion of the applications. Therefore, this criteria was not evaluated.

A list of all attendees, a sign-in log and informational materials were not provided by GDIT 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. This report is based on the receivers and respondses to an email correspondes from August 1.

CONCLUSION

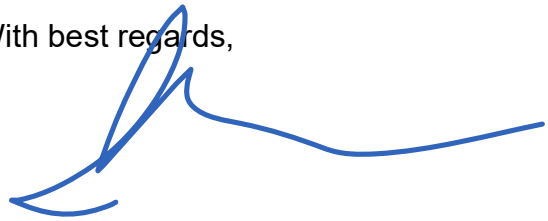
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Scientific Review Council Meeting (22.2_SRC)
Observation Report

Report No.	2022-09-01 22.2_SRC
Program Name:	Academic Research
Panel Name:	22.2 Scientific Review Council Meeting (22.2 _SRC)
Panel Date:	September 1, 2022
Report Date:	September 2, 2022

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 22.2 Scientific Review Council Meeting (22.2_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on September 1, 2022.

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: Thirty-two (32) applications were discussed
- Panelists: One (1) panel chair, and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: One (1)
- 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 was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Three applications from cycle 22.10 REC was added to the aganda on the day of the meeting.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Recruitment Cycle 22.10

Awards Announced at the August 17, 2022, and September 14, 2022, Oversight Committee Meetings

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 *Recruitment of Established Investigators* and *Recruitment of First-Time, Tenure-Track Faculty Members*..

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	Nominator/Principal Investigator	Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
RR220094	Mary Dickinson	Baylor College of Medicine	E. Fearon
Applications not considered by the PIC or Oversight Committee:			
RR220109	Michael Blackburn	The University of Texas Health Science Center at Houston	P. Jones

De-Identified Overall Evaluation Scores

Recruitment of First-Time, Tenure-Track Faculty members

Academic Research Recruitment Cycle 22.10

Application ID	Final Overall Evaluation Score
RR220094▾	1.0
RR220101▾	1.0
af[a]	1.6
RR220097*	1.6
RR220092*	2.0
aa	2.2
ab	3.0
ac	3.0
ad	3.0
ae	3.5

[a] This application was withdrawn by the applicant before the Scientific Review Council voted whether or not to make a final recommendation on it.

* Recommended for grant award by Scientific Review Council on September 1, and subsequently the PIC on September 6, 2022.

▾ Approved for award by the Oversight Committee on August 17, 2022.

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.

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@health.ucsd.edu

San Diego Branch
UC San Diego School of Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0660
La Jolla, CA 92093-0660

T 858 534 7804
F 858 534 7750

August 2, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

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

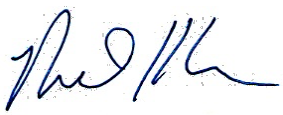
Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on on May 12, 2022 (REC Cycle 22.10), July 14, 2022 (REC Cycle 22.10) and August 1, 2022 (REC Cycle 22.10) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, and Recruitment of First-Time, Tenure Track Faculty Members.

The SRC recommends two applications, which are inlcuded on the attached list. The recommended funding amounts and the overall evaluation scores are stated for the grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $4,000,000

The recommendation meets the SRC's standards for funding. These include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, 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

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Rank	App. ID	Mechanism	Candidate	Organization	Budget	Overall Scores
1	RR220094	RFTFM	Steven Boeynaems, Ph.D.	Baylor College of Medicine	$2,000,000	1.0
2	RR220101	RFTFM	Siqi Liu, Ph.D.	The University of Texas Southwestern Medical Center	$2,000,000	1.0

RFTFM = Recruitmen of First-Time, Tenure Track Faculty Members

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

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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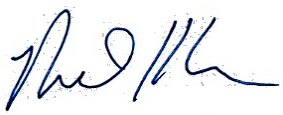
Sincerely yours,



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

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

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RFTFM = Recruitmen of First-Time, Tenure Track Faculty Members

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Core Facility Support Awards

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-22.2-CFSA

Core Facility Support Awards

Please also refer to the Instructions for Applicants document, which will be posted on October 13, 2021

Applications for this award mechanism are subject to institutional limits. Applicants are advised to consult with their institution's Office of Research and Sponsored Programs (or equivalent).

Application Receipt Opening Date: October 13, 2021

Application Receipt Closing Date: January 12, 2022

FY2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

TABLE OF CONTENTS

RFA VERSION HISTORY

08/30/21 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 $6 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.
- 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
- 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
- Expansion of access to innovative clinical trials

2. RATIONALE

Core Facility Support Awards seek to facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. A user group of Texas-based investigators must be identified, each of whom should have supported cancer research projects that will make use of the requested facility. This requirement is not intended to exclude early-career–stage investigators who have not yet secured peer-reviewed grant support. Successful applicants should be working in a research environment capable of supporting potentially high-impact cancer studies.

CPRIT is particularly interested in supporting core facilities that provide services to cancer investigators from multiple Texas institutions and that address CPRIT Program Priorities.

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 RFA solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of 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 survivorship. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, cure, or quality of life. This award provides cancer researchers access to appropriate research infrastructure, instrumentation, and technical expertise necessary to achieve their research objectives.

Funds may be requested to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. **CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions.**

4. FUNDING INFORMATION

The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of $4,000,000 in total costs.

Allowable expenses include the cost of instruments (must be expended in the first 2 years), installation and/or necessary renovation expenses in the first year (installation/renovation expenses not to exceed 10% of the total first-year request), and maintenance/service contracts.

Installation/renovation expenses can be requested in the first year only. Equipment must be purchased within the first 2 years. Applicants may request salary support and fringe benefits for the facility director, data analysts, and technical staff. Travel to scientific/technical meetings or collaborating institutions is also an allowable expense for these individuals. Note all international travel must receive prior approval by CPRIT. *All of these costs and expenses must be prorated for direct use in cancer research efforts.* Also allowable are funds to support the use of the facility by qualified cancer research investigators for relevant projects (research supplies and services, clinical research costs, etc). Institutions must describe and justify the process to be used to disburse funds to support use of the facility by cancer investigators. Finally, some fraction of available funds may be used by the facility director for development of new or improved approaches to technical challenges.

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 be the director of the facility and 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. The PI should also hold a faculty position, preferably at the level of associate or full professor or the equivalent.

- The PI must commit a minimum 10% level of effort throughout the entire award period.
- This award must be directed by the PI. Multi-PIs are not permitted.
- 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. Collaborators should have specific and well-defined roles. 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. In no event shall equipment purchased under this award leave the State of Texas.
- **An institution may submit only 1 application (1 new, 1 renewal, or 1 resubmission) under this RFA during this funding cycle. An exception will be made for institutions submitting applications for core facilities that support research totally directed toward childhood and adolescent cancer; in this case, institutions may submit 1 childhood and adolescent cancer application and 1 additional application in another aspect of cancer research (new, renewal, or resubmission).**
- For purposes of this RFA, an institution is defined as that component of a university system that has a geographically distinct campus.
- Academic institutions and health science centers that are components of the same university system and share a contiguous or near-contiguous campus are eligible tosubmit a single application.
- An institution may only resubmit an application that was previously not funded once (see section 6).
- Support for only 1 facility may be requested per application. Applications that propose to provide services to researchers at multiple institutions are permitted and encouraged. However, such collaboration must not be used as a pretext for supporting more than 1 facility at a given institution.
- The coherence of the facility and the ability of the PI to oversee all of the facility's operations will be critical components of the review process. If support is requested for an existing facility, applicants must make it clear how CPRIT support will enhance its

capabilities and improve access for cancer investigators rather than simply replace ongoing institutional support.

- An individual may serve as a PI or Multi-PI on no more than 3 active Academic Research grants. Recruitment grants and research training awards do not count toward the 3-grant maximum; however, CPRIT considers project leaders on a MIRA award 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 8/31/2022).
- 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 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. 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 per application is not permitted.

7. RENEWAL POLICY

Renewal applications for existing Core Facility Support Awards will be accepted in response to this RFA.

Renewal applications must demonstrate a compelling justification for continued CPRIT support of the facility that is based upon the scientific impact of continued CPRIT support. Quality and cost-efficiency of the services alone are not sufficient justifications for continued CPRIT support. Renewal applications will be expected to demonstrate an exceptional record of impact on cancer research as measured by:

- Utilization (number of PIs utilizing facility; number of institutions served);
- Publications that cite CPRIT support;
- New peer-reviewed grant awards supported;
- Clinical trials supported;
- Patents supported.

The applicant should time the submission of the renewal application so that the new contract execution date for the grant award comes after the contract expiration date of the initial CPRIT award; any overlap in funding should be avoided. In the event, that a renewal application is funded prior to the expiration date of the current CPRIT award, an early termination of the current award is required.

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. 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 October 13, 2021and must be submitted by 4 PM central time on January 12, 2022. **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 extenuating circumstances. 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 *IFA* 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 rejected without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the proposed program, including a summary of the facility to be developed, an outline of the goals of the research projects that will be supported, and an overview of institutional infrastructure and commitment. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the core facility plan. Clearly address how the proposed project, if successful, will have a major impact on cancer.

If the application is a renewal of an existing CPRIT funded resource, the abstract must state the impact of the resource and document why continued CPRIT support is justified.

Note: 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. 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).

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 9.1) 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 if the award is made.

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. Institutional Support (2 pages)

Each application must be accompanied by a strong letter of institutional support from the president or provost or equivalent indicating commitment to the program and certifying that this is the sole application submitted by this institution in response to this RFA. Furthermore, the

letter should indicate any support of the facility for activities not related to cancer research. The letter should address the institutional oversight ensuring that the facility will be operated in a superior fashion and discussing how this will be ascertained. If the application is a renewal of an existing CPRIT-funded resource, a compelling justification for continued CPRIT support of the resource must be provided.

8.2.6. Resubmission Summary (1 page)

An application previously submitted to CPRIT but not funded may be resubmitted **once** after careful consideration of the reasons for lack of prior success. 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.

8.2.7. Renewal Summary (2 pages not including facility impact tables)

Applicants preparing a renewal of a CPRIT-funded core facility must describe and demonstrate that exceptional progress has been made on the current funded award and demonstrate a compelling justification for continued CPRIT support of the facility that is based upon the scientific impact of continued CPRIT support. Quality and cost-efficiency of the services alone are not sufficient justifications for continued CPRIT support.

Using facility impact forms provided list, for the prior grant funding period, the number of PIs utilizing the facility and the institutions served (Table 1), the peer-reviewed grants resulting from facility support (Table 2), publications (published and in press) citing utilization of the facility (Table 3), clinical trials utilizing the facility (Table 4), and patents filed or granted that have resulted from work supported by the facility (Table 5).

The following 5 tables displayed below are required. **Note that the utilization parameters and table formats should follow the instructions for completing the CPRIT annual progress report.** Refer to the Table templates in the document located in *Current Funding Opportunities* for Academic Research in CARS.

Table 1: Utilization of the facility by PIs (provide the total number of PIs that have utilized the facility by PI's institution)

Table 2: Additional/Follow-On Funding (provide information in Table 2 about the funding source, type of funder, grant ID, title of grant, total amount received (direct plus indirect costs

over the entire performance period), total project period of investment/award, a description of the subject of the funding, PI of the grant, and PI's organization.

Funding Source	*Type of Funder*	*Award ID*	*Title of Grant*	*Total Amount Received (Direct and Indirect Costs for All Years)*	*Total Project Period of Investment/Award*	*Investment/Award Description*	*PI*	*PI Organization*

Table 3: Publications citing the facility Enter information about each publication in the table. Information includes PubMed ID, author, title, journal, and publication date.

Table 4: Clinical trials supported by the facility Enter trial name, clinicaltrials.gov identifier, clinical research categories (interventional and observational), primary purpose, primary anatomic cancer site, phase, clinical trial focus, clinical trial site, and patients enrolled.

Table 5: Filed/granted patents resulting from research supported by the facility Enter patent number, inventors, patent title, description, date of publication or issue, and date the patent application was filed and/or granted.

8.2.8. Core Facility Plan (5 pages)

Background: Present the rationale and need for the facility, emphasizing the pressing problems in cancer research that will be addressed. Address the research community served and if researchers at other institutions will have access. Address how the proposed facility does not duplicate services provided by existing facilities. Address how the proposed facility addresses CPRIT priorities.

Instrument Details: Provide details of the equipment/instruments, if any, that will be acquired.

Technical Expertise: Describe the qualifications of the facility director and other key personnel that make them suitable to oversee the establishment and operations of the facility.

Administrative Plan:

1. Clearly describe the plan under which the operation, sharing, time allocation, and maintenance of the facility will be administered.

2. Discuss in detail the plan for cost recovery and charge backs for core services. If a cost recovery plan is not included in the administrative plan, provide strong justification for its absence.
3. Discuss whether cancer researchers from other Texas academic institutions or industry scientists have access to the facility and the terms for such access.
4. Discuss if funds will be allocated to support the use of the facility by qualified cancer research investigators and describe the process to be used to disburse funds to support use of the facility by these cancer investigators. If some fraction of available funds is to be used by the facility director for development of new or improved approaches to technical challenges, discuss the process to identify and evaluate such development projects.

Training Plan: Describe the plan to train users to use the facility and to evaluate the results obtained.

Evaluation Plan: Describe an evaluation plan for the facility.

Sustainability: Describe in detail the plans for continuation of the core facility service at the conclusion of the CPRIT award, such as documentation of institutional support and additional award mechanisms and/or user fees.

8.2.9. Documentation That the Proposed Core Facility Does Not Duplicate Existing Services (2 pages)

In this section, provide a comprehensive list of existing cores or facilities in Texas that offer researchers access to technology and services similar to that proposed in this application. Explain why the proposed core is not duplicative of these and is required to support the research of the users of the new core proposed in this application.

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

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

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 clear justification of the budget, demonstrating need 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. 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 administratively withdrawn.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award 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. The PI must commit a minimum 10% level of effort throughout the entire award period.

- The PI is expected to attend CPRIT's Conference. CPRIT funds may be used to send up to 2 people to the conference.

8.2.13. User Group (8 pages)

Provide concise descriptions of the research projects of major users of the facility. Provide a tabular summary of all users of the requested facility. List the names of all researchers, their academic appointment and affiliation, include user grant-funded award data (project title(s)/number(s), award grant ID, award duration), a brief description of the project(s), and approximate percentage use of the facility for direct use in cancer research efforts. Discuss whether cancer researchers from other Texas academic institutions or industry scientists have access to the facility and the terms for such access. CPRIT will look with special favor on the development of core facilities that serve multi-institutions.

8.2.14. Biographical Sketches (5 pages each)

The PI should provide a biographical sketch that describes his/her education and training, professional experience, awards and honors, and publications relevant to cancer research.

A biographical sketch must be provided for the PI (as required by the online application receipt system). Up to 5 additional biographical sketches for key personnel from the user group may be provided. Each biographical sketch must not exceed 5 pages.

8.2.15. Current and Pending Support

State 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 must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

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

Applicants are required to 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.

8.2.17. 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 withdrawn.

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 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 forcancer 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. Review Process Overview

All eligible applications will be evaluated using a 2-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council (SRC). 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 below. 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 SRC based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by the SRC 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, **Texas Administrative Code, Title 25, chapters 701 to 703.**

9.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, SRC 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 SRC 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, Texas Administrative Code, Title 25, chapters 701 to 703.

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 an SRC 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. The prohibition on communication does not apply to the time period prior to the opening of CARS. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.3. Review Criteria

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.**

9.3.1. 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 request for the instrument/equipment. Primary criteria include the following:

Justification of Need/Value: Is the uniqueness of the facility addressed? Is the need for the facility justified? Is it necessary and appropriate for the research projects? Will the state-of-the-art facility directly support and impact cancer research programs at the institution and in the region? How will the availability of the facility offer incipient research projects by investigators at various career stages the opportunity to develop? Will the facility make the user group more competitive for external funding? Will the facility provide cancer researchers from other Texas academic institutions or industry scientists access to the facility? Does the facility address CPRIT priorities?

If this is a renewal application, is there evidence that the facility has had an exceptional impact on the cancer research and will the renewal provide further innovation and impact.

Quality and Significance of research projects supported: Does the facility support a significant number of different, independently funded users? Are the projects at the forefront of cancer research? Are the projects of significance in reducing cancer incidence, morbidity, or mortality?

Technical Expertise: Is there sufficient technical expertise for optimal use of the facility? How well qualified is the user group to take optimal advantage of the facility and evaluate the research results for the proposed projects? How will the facility be maintained? Is there a satisfactory training plan for new users?

Administration: Is there assurance that the facility will be managed and operated in a superior fashion? To whom does the facility director report? Is that person committed to appropriate oversight (a letter of commitment should be submitted)? Is there an adequate plan for the management of the facility, including an appropriate system for charging for services and subsidy of user fees for specific cancer-related projects and individuals (especially early-career-stage investigators)? How will facility time be allocated among the projects? Have biosafety issues been addressed? Are there criteria and is there a mechanism for prioritization of user requests? Are there appropriate advisory committees?

Institutional Commitment: Is there clear institutional commitment for support of the facility for cancer research? Has the host institution provided an appropriate site for the facility?

9.3.2. Secondary Criteria

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

Secondary criteria include the following:

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

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human biological samples are included in the proposed research, is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed? Note that certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

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	August 30, 2021

Application

Online application opens	October 13, 2021, 7 AM central time
Application due	January 12, 2022, 4 PM central time
Application review	January 2022 to August 2022

Award

Award notification	August 17, 2022
Anticipated start date	August 31, 2022

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 Texas Administrative Code, Title 25, chapters 701 to 703.

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 Texas Administrative Code, Title 25, chapters 701 to 703.

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, Texas Administrative Code, Title 25, chapters 701 to 703.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals documented in the grant award contract and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate.

CPRIT will review annual progress reports and continuation of funding is contingent upon the timely receipt of these reports and documentation of sufficient progress toward completing project goals. 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. 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, Texas Administrative Code, Title 25, chapters 701 to 703, for specific requirements regarding 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 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 Program Manager for Academic Research.

Tel: 512-305-8491

Email: research@cprit.texas.gov

Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT) 22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR) (22.2 AR C/TCR) Observation Report

Report No.	2022-04-26 22.2_AR_C/TCR
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR (22.2 _AR_C/TCR)
Panel Date:	April 26, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR (22.2_AR_C/TCR) meeting. The meeting was chaired by Richard O'Reilly and Margaret Tempero and conducted via videoconference on April 26, 2022.

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: Nineteen (19) applications were discussed, and eleven (11) applications were not discussed
- Panelists: Two (2) panel chairs, twenty-one (21) expert reviewers, and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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) Conflicts of Interest (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

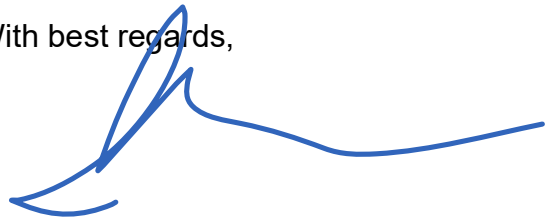
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research Review Panel - Cancer Biology
(22.2_AR_CB)
Observation Report

Report No.	2022-04-27 22.2_AR_CB
Program Name:	Academic Research
Panel Name:	22.2 Academic Research Review Panel - Cancer Biology (22.2 _AR_CB)
Panel Date:	April 27, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research Review Panel - Cancer Biology (22.2_AR_CB) meeting. The meeting was chaired by Peter Jones and conducted via videoconference on April 27, 2022.

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: Thirteen (13) applications were discussed and fifteen (15) applications were not discussed
- Panelists: One (1) panel chair, sixteen (16) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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.

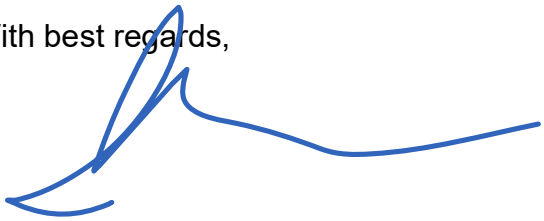
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Basic Cancer Research Panel-1 (22.2_AR_BCR-1)
Observation Report

Report No.	2022-04-28 22.2_AR_BCR-1
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Basic Cancer Research Panel-1 (22.2 _AR_BCR-1)
Panel Date:	April 28, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Basic Cancer Research Panel-1 (22.2_AR_BCR-1) meeting. The meeting was chaired by Steven Fiering and Bart Williams and conducted via videoconference on April 28, 2022.

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: Ten (10) applications were discussed and eight (8) applications were not discussed
- Panelists: Two (2) panel chairs, ten (10) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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) Conflicts of Interest (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

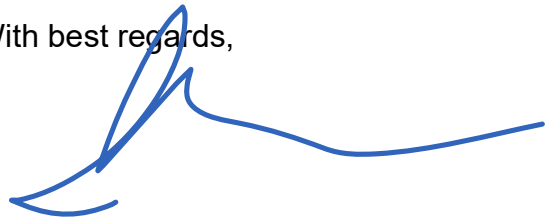
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Imaging Technology and Informatics (22.2_AR_ITI)
Observation Report

Report No.	2022-04-29 22.2_AR_ITI
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Imaging Technology and Informatics (22.2 _AR_ITI)
Panel Date:	April 29, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Imaging Technology and Informatics (22.2_AR_ITI) meeting. The meeting was chaired by Martin Pomper and conducted via videoconference on April 29, 2022.

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: Twelve (12) applications were discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, seventeen (17) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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 six (6) Conflicts of Interest (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

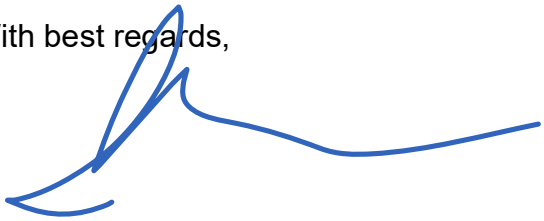
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Basic Cancer Research Panel-2 (22.2_AR_BCR-2)
Observation Report

Report No.	2022-05-05 22.2_AR_BCR-2
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Basic Cancer Research Panel-2 (22.2 _AR_BCR-2)
Panel Date:	May 5, 2022
Report Date:	May 9, 2022

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 22.2 Academic Research - Basic Cancer Research Panel-2 (22.2_AR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via videoconference on May 5, 2022.

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: Ten (10) applications were discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, Fourteen (14) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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.

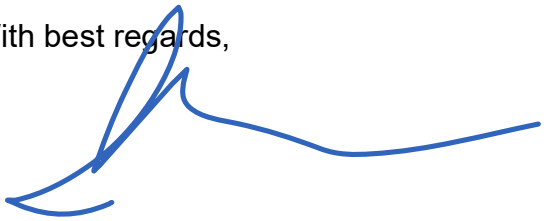
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Scientific Review Council Meeting (22.2_SRC)
Observation Report

Report No.	2022-09-01 22.2_SRC
Program Name:	Academic Research
Panel Name:	22.2 Scientific Review Council Meeting (22.2 _SRC)
Panel Date:	September 1, 2022
Report Date:	September 2, 2022

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 22.2 Scientific Review Council Meeting (22.2_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on September 1, 2022.

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: Thirty-two (32) applications were discussed
- Panelists: One (1) panel chair, and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: One (1)
- 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 was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Three applications from cycle 22.10 REC was added to the aganda on the day of the meeting.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Cycle 22.2

Awards Announced at the September 14, 2022, 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 22.2 include: *Core Facility Support Awards; Clinical Trials Network Award; Early Clinical Investigator Award;* and *High-Impact/High-Risk Research 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	Principal Investigator	Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
RP220553	Wen Jiang	The University of Texas M. D. Anderson Cancer Center	K. Swanson
RP220599	Peter Houghton	The University of Texas Health Science Center at San Antonio	J. Conejo-Garcia
RP220543	Jason Park	The University of Texas Southwestern Medical Center	W. Kast
RP220631	Min Kang	Texas Tech University Health Sciences Center	W. Kast
RP220562	Kenneth Hoyt	The University of Texas at Dallas	K. Zinn
RP220645	Georgios Alexandrakis	The University of Texas at Arlington	A. Chatziioannou
Applications not considered by the PIC or Oversight Committee:			
RP220563	Siyuan Zheng	The University of Texas Health Science Center at San Antonio	J. Conejo-Garcia
RP220622	Aimin Liu	The University of Texas at San Antonio	J. Conejo-Garcia

Application ID	Principal Investigator	Organization	Conflict Noted by Reviewer
RP220557	Steven Berk	Texas Tech University Health Sciences Center	W. Kast
RP220591	Carl Allen	Baylor College of Medicine	W. Kast
RP220642	Gulio Draetta	The University of Texas M. D. Anderson Cancer Center	W. Kast
RP220617	Sherry Yennello	Texas A&M University	D. Mankoff
RP220682	Yichen Ding	The University of Texas at Dallas	A. Chatziioannou;A. Wu
RP220688	Girgis Obaid	The University of Texas at Dallas	K. Zinn

De-Identified Overall Evaluation Scores

Core Facility Support Awards

Academic Research Cycle 22.2

Application ID	Final Overall Evaluation Score
RP220582*	1.0
RP220646*	1.8
RP220662*	1.9
RP220631*	1.9
RP220599*	2.3
RP220587*	2.3
Ba	2.6
Bb	2.7
Bc	3.4
Bd	3.6
Be	3.8
Bf	4.0
Bg	4.3
Bh	4.6
Bi	4.7
Bj	4.7
Bk	4.7
Bl	5.3
Bm	5.3
bn	6.0
Bo	6.2
Bp	6.3
Bq	7.3

* Recommended for funding

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.

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@health.ucsd.edu

San Diego Branch
UC San Diego School of Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0660
La Jolla, CA 92093-0660

T 858 534 7804
F 858 534 7750

September 1, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

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

Dear Dr. Patel and Mr. Roberts,

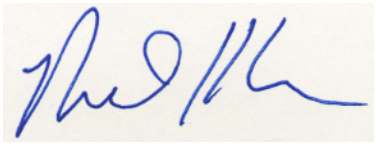
The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Early Clinical Awards, Core Facility Support Awards, Clinical Trials Network Award and High-Impact/Hight Risk Awards.

The SRC met on September 1, 2022 to consider the applications recommended by the peer review panels following their meetings held April 26, 2022 to May 5, 2022.

Recommended funding amounts and the overall evaluation score are stated for each grant application The total amount for the applications recommended is $32,768,514.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing CPRIT's long term goals to achieve a decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products.

Sincerely yours,



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

ID	Award RFA	Score	Application Title	PI	PI Organization	Recommended Budget
RP220582	CFSA	1.0	Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UTSouthwestern Medical Center	Rosen, Michael	The University of Texas Southwestern Medical Center	$4,000,000
RP220646	CFSA	1.8	Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas	Lewis, Michael	Baylor College of Medicine	$3,999,996
RP220544	ECI	1.8	CPRIT Early Clinical Investigator Award-Christopher Alvarez-Breckenridge	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,500,000
RP220606	HIHRRA	1.9	Developing a Novel Optogenetic Recombinase System to Study and Target Metastatic Cancer	Maddipati, Ravikanth	The University of Texas Southwestern Medical Center	$250,000
RP220662	CFSA	1.9	UTHSCSA Cancer Genome Sequencing and Computation Core	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$3,998,688
RP220650	HIHRRA	1.9	Targeting Nitric Oxide Synthase (NOS) Pathway to Remodel Obesity-Induced Tumor Inflammation in Patients With TNBC	Chang, Jenny	The Methodist Hospital Research Institute	$250,000
RP220631	CFSA	1.9	West Texas Pharmacology Core	Kang, Min	Texas Tech University Health Sciences Center	$3,369,480
RP220542	CTNA	1.9	Establish the Accelerating Clinical Oncology Research Network-Texas (ACORN-TX) to Enhance Clinical Trial Access in North and Central Texas	Beg, Muhammad	The University of Texas Southwestern Medical Center	$3,000,000
RP220626	HIHRRA	2.0	A Glia-to-Neuron Conversion for Treating Oral Cancer Pain	Tao, Feng	Texas A&M University System Health Science Center	$237,500

RP220558	HIHRRA	2.0	Novel Covalent Drugs for BCL6	Fast, Walter	The University of Texas at Austin	$249,999
RP220614	HIHRRA	2.0	Understanding the Impact of Immunity on Premalignant Somatic Mosaicism and Cancer Prevention	Zhu, Hao	The University of Texas Southwestern Medical Center	$237,501
RP220666	HIHRRA	2.0	Targeting Tumors and the Tumor Microenvironment With Banana Lectin-Expressing T Cells	McKenna, Katie	Baylor College of Medicine	$250,000
RP220567	HIHRRA	2.0	Fasting-Induced Microbiome Changes and Radioprotection	Piwnica-Worms, Helen	The University of Texas M. D. Anderson Cancer Center	$249,999
RP220645	HIHRRA	2.0	Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy	Alexandrakis, Georgios	The University of Texas at Arlington	$250,000
RP220581	ECI	2.1	Hyperspectral, Quantitative Intraoperative Fluorescence Image-Guided Brain Surgery	Urban, Randall	The University of Texas Medical Branch at Galveston	$1,494,784
RP220599	CFSA	2.3	Texas Pediatric Cancer Testing (TPCT) Core	Houghton, Peter	The University of Texas Health Science Center at San Antonio	$3,935,480
RP220653	HIHRRA	2.3	Novel Modulators of Genomic Instability in Human Cells	Vasquez, Karen	The University of Texas at Austin	$249,932
RP220587	CFSA	2.3	Advanced Protein Therapeutics Core	Maynard, Jennifer	The University of Texas at Austin	$3,995,180
RP220592	HIHRRA	2.4	Restoration of Phagocytosis Function of Glioma-Associated Microglia/Macrophage by Activating QKI-PPARb-RXRa	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	$250,000
RP220600	HIHRRA	2.4	In Vivo Akt Analysis via Chemical Genetics and Nanoparticle-Mediated Probe Delivery	Wang, Degeng	Texas Tech University	$249,999
RP220610	HIHRRA	2.8	Identification of Enhancers of T-Cell Antitumor Activity in PDAC Using CRISPR Activation Screening	Maitra, Anirban	The University of Texas M. D. Anderson Cancer Center	$250,000

RP220553	HIHRRA	2.9	Reversing Aging-Associated Resistance to Cancer Immunotherapy	Jiang, Wen	The University of Texas M. D. Anderson Cancer Center	$249,976
RP220639	HIHRRA	2.9	Targeting NHE6 to Improve Clinical Efficacy of Daratumumab in Myeloma	Yang, Jing	The Methodist Hospital Research Institute	$250,000

CFSA – Core Facility Support Awards
CTNA - Clinical Trials Network Awards
ECI – Early Clinical Investigator Awards
HIHRA – High-Impact/High Risk Awards

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Clinical Trials Network Award

Request for Applications

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-22.2-CTNA

Clinical Trials Network Award

Please also refer to the Instructions for Applicants document, which will be posted on October 13, 2021

Application Receipt Opening Date: October 13, 2021

Application Receipt Closing Date: January 12, 2022

FY2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

TABLE OF CONTENTS

RFA Version History

08/30/21 RFA release

Rev 08/31/21 Section 10 – Key Dates

- Edited to remove ambiguity regarding Award Notification Date and Anticipated Start Date

1. OVERVIEW

The Cancer Prevention and Research Institute of Texas (CPRIT) aspires to develop a statewide clinical trials network to increase access by cancer patients in Texas to state-of-the-art clinical trials of new cancer treatment strategies. As an initial step in realizing this goal, CPRIT developed the Clinical Trials Network Award (CTNA) to support new clinical trials networks in Texas in order to provide oncologists and their patients who currently have limited access to cancer therapeutic trials and as a consequence limited opportunities to participate in cancer trials.

The CTNA will be made to a Lead Institution (LI) to develop and oversee a network of 2 cancer care facilities (Network Affiliates) (Stage 1). Once the initial network is satisfactorily demonstrated, the LI will be eligible to receive additional CPRIT funding to expand its network to 2 additional facilities located outside the LI current catchment (Stage 2).

LIs will provide their Network Affiliates access to phase 2 and phase 3 clinical trials appropriate for the patient population served by the affiliates. LIs and Network Affiliates are required to use acommon institutional review board (IRB) either provided by the LI or a central IRB and to share access to a web-based clinical trials management support system (CTMS) and agree to implement appropriate legal and contractual agreements necessary to allow data sharing and clinical trial oversight. Ultimately, CPRIT intends to link successful LI networks into a statewide Texas Cancer Clinical Trials Network.

2. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 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.

2.1. 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 about how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- 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
- Expansion of access to innovative clinical trials

3. RATIONALE

The past decade has spawned new strategies to treat patients with cancer. Technology has enabled scientists and clinicians to dissect individual patients' cancers down to the very genes that cause them to grow and progress, thereby opening new doors to the development of treatment specific for that patient. This Precision Cancer Medicine, as it has been named, requires tests or biomarkers to determine the gene/protein drivers of a given cancer and then new drugs that effectively target and block those drivers. Industry and academic centers have responded by developing new drugs that target these defective pathways, resulting in a plethora of new agents that need testing in patients. The sheer number of these new drugs and the requirement that they be tested only in the subset of patients harboring the gene/pathway alteration have made clinical testing of these new agents challenging. No longer do we test a new

drug on all patients or all patients with a specific disease like breast or colon cancer. Now these drugs must be tested on a much smaller subset of patients defined by the abnormal driver pathway in their tumor. This has resulted in the need to increase the number of patients going on clinical trials beyond the 3% to 5% of cancer patients that now participate in clinical research trials.

Another important issue is that many patients who could benefit or desire to participate in a new drug trial don't have access to those trials because (1) they are from an underserved or underinsured population without access to a cancer center, (2) they do not have close geographic access to an urban cancer center where most of these trials are offered, or (3) they can't afford to travel to another destination and stay there for the duration of the clinical trial. This problem often gives rise to a selection bias for the trial in that only insured, white, male, urban patients are studied in a clinical trial. It is recognized that different ethnic or racial groups may respond differently to a drug and need to be captured in early trials before a new drug enters the marketplace. Thus, solutions to address these issues must consider bringing the trials closer to the patients or providing support to bring the patients to the trial if it can't be done locally. These problems are particularly important in large states like Texas where patients are often hundreds of miles from an academic urban clinical research center offering state-of-the-art clinical trials of new and promising treatments.

There are other barriers to increasing access to clinical trials other than patient financial and geographic concerns, and these relate in part to the medical care available in a smaller community:

1. Oncologists don't have the necessary resources or time to establish a clinical trials program that includes an experienced research pharmacist, research nurse, study coordinator, and other staff that are critical for a busy physician to enter patients on a clinical trial.
2. Community physicians may not have the experience, knowledge, or resources to carry out clinical trial research; for example, there are many regulatory requirements that need to be followed to ensure patient safety and to address other legal issues.
3. Community physicians may not be interested in this aspect of patient care.
4. Substantial regulatory and legal matters must be addressed to open clinical trials.

5. Certain trials such as sophisticated immune therapy trials with adoptive T-cell or CAR-T cell therapies, trials involving bone marrow transplantation, or those requiring repeated tumor biopsies to learn if the tumor is responding or resistant to therapy can only be done in experienced centers of excellence.

4. RESEARCH OBJECTIVES

The goal of the CTNA is to inaugurate new clinical trials networks in Texas in order to provide oncologists and their patients who currently have limited access to cancer therapeutic trials opportunities to participate in cancer trials. This mechanism will support access to phase 2 and 3 cancer therapeutic trials appropriate for a community oncology care setting. Clinical trials evaluating surgical or radiation cancer therapies or imaging are not appropriate for this mechanism. Clinical trials evaluating behavioral or prevention services are not appropriate for this mechanism.

To inaugurate this program, CPRIT plans to provide, on a competitive application basis, resources to **LIs with existing robust cancer clinical trials operations** to support development and operations of a clinical trials network with oncology care facilities that currently have limited access to clinical trials (**Network Affiliate**).

LIs will provide their Network Affiliates access to phase 2 and selected phase 3 trials that are appropriate for a community practice setting and meet the needs of that affiliate's patient population.

With award funds, the LI will provide their Network Affiliates access to a web-based protocol management system; consent forms tailored to meet the language, cultural, and socioeconomic needs of the patient population served; data safety and quality control monitoring; training of research personnel, including opportunities to receive CME, CNE, and ACRP maintenance certifications; and access to LI tumor boards with capability for virtual meeting participation to assess patient eligibility for clinical trials.

Network Affiliates are required to identify a physician champion (**physician leader**) who will provide overall leadership at their site, demonstrate onsite research pharmacy capability, and identify clinical research personnel responsible for patient eligibility determination, protocol registration, data collection, and adverse event reporting.

Network Affiliates will be expected to use the LI's IRB or a central IRB to ensure timely activation of clinical trials.

Network Affiliates will be expected to enter into appropriate legal and contractual arrangements with the LI to allow HIPAA business associate status, data sharing, and EMR access.

Network Affiliates will be expected to demonstrate capability for processing and storing plasma and biosamples.

Metrics of success include the following:

1. Ability to evaluate trial eligibility for all new patients and enter eligible patients on therapeutic trials.
2. Satisfactory performance on quality control and clinical protocol monitoring and audit evaluations.
3. Satisfactory staff training and demonstration of continued learning.
4. Ability of Network Affiliate to enroll patients with molecularly defined subsets.
5. Referral of Network Affiliate patients suitable for more complex trials to the LI.

Once the Stage 1 Network is satisfactorily demonstrated, the LI will submit to CPRIT the Stage 2 plan to support expansion of the LI's Network Affiliates to up to 2 additional community-based practices that are geographically located outside the LI catchment. Note that for the purpose of this award, the LI catchment is the geographic region where greater than 80% of the LI patients reside.

5. FUNDING INFORMATION

Applicants may request a maximum of $600,000 annually for Stage 1 and a maximum of $900,000 annually for Stage 2. The maximum project period is 4 years.

Allowable costs include the following:

- Funds may be used for personnel salary and fringe benefits, research supplies, equipment, CTMS licensing fees, cost for central IRB review, and travel of personnel between LI and Networks sites (see section 8.2.9).

- Support up to 20% effort for the LI PI and 10% effort for the Network Affiliate physician leader are required up to a maximum full-time salary of $200,000/year.
- Subject participation costs including diagnostic or interventional procedures associated with participation in a clinical trial and not considered routine standard of care should be supported by other mechanisms and are not appropriate for this award but may be counted toward the required matching funds (see section 12).
- Please see section 8.2.9 and the IFA for additional information.

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 5% indirect cost expenditures may be distributed between the LI and the Network Affiliate(s); however, in no case may the actual indirect costs reported exceed 5% of grant funds expended. The LI determines whether or not a portion of the 5% indirect costs may be claimed on grant expenses submitted by a Network Affiliate to the LI.

6. ELIGIBILITY

- The LI and Network Affiliates must be Texas-based entities. The LI and Network Affiliates may be institutions, organizations, or other entities (including physician groups) that conduct clinical research; however, a public or private company operating as a clinical research organization (CRO) is not eligible for funding under this award mechanism.
- An entity may only submit 1 application as the LI under this RFA. NetworkAffiliates may be listed on 1 application submitted under this RFA.
- An entity may hold only 1 active CTNA.
- The Principal Investigator (PI) must have an MD or DO and must be a full-time resident of Texas at the time the application is submitted and during the entire time the grant is active.
- An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants at the time of CTNA. Recruitment 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 August 31, 2022).

- A PI may submit both an application to this RFA and a new or renewal application to another RFA during this funding cycle.
- This award does not allow Multiple PIs. Coinvestigators are allowed.
- Collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but those organizations outside Texas are not eligible to receive CPRIT grant 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 gift or grant to CPRIT or to any nonprofit organization specifically created to benefit CPRIT.
- Texas law prohibits a LI or Network Affiliate from receiving CPRIT grant funding if a CPRIT Oversight Committee member or the spouse of a CPRIT Oversight Committee member is employed by the LI or Network Affiliate, participates in the management of the LI or Network Affiliate, or owns or controls, directly or indirectly, an interest in the LI or Network Affiliate.
- The applicant must report whether the LI or Network Affiliate, 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.

7. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted and must follow all resubmission guidelines. An application is considered a resubmission if the proposed LI is the same as presented in the original submission. Note that the PI and Network Affiliates can be changed in a resubmission.

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 apply. 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 October 13, 2021 and must be submitted by 4 PM central time on January 12, 2022. **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 extenuating circumstances. 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 6 will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Describe the proposed clinical trials network including a description of the LI and proposed Network Affiliates for Stage 1 of the network plan. Discuss the clinical trial capabilities of the LI and the criteria for selection of Network Affiliates. Discuss opportunities for expansion of the network in Stage 2. Identification of the Stage 2 Network Affiliates is not required at the time of application. Address how the LI will oversee the proposed network and how the performance of the Network Affiliates will be monitored and evaluated. Provide a clear and concise plan to implement the legal and operational agreements to allow the data sharing, EMR access, and HIPAA business associate contracts necessary to establish the network.

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

Provide a layperson's summary of the proposed clinical trials network including description of the participant sites and patient populations served. Describe, in simple, nontechnical terms, how the network will facilitate access to clinical trials, the type(s) of trials proposed for the network, and the expected impact on patient access to clinical trials. 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 9.1) 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 CTNA including the plan for launching Stage 1 and for implementing Stage 2 by Year 3 of the award. These goals and objectives will also be used during the submission and evaluation of progress reports and overall assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked in the implementation and evaluation of the network. 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 (1 pages)

An application previously submitted to CPRIT but not funded may be resubmitted after careful consideration of the reasons for lack of prior success. Applicants preparing a resubmission must describe the approach to the resubmission and address all noted concerns raised in the review of the original application.

8.2.6. Network Description (10 pages)

A. Principal Investigator

Discuss the qualifications and the role of the Principal Investigator.

B. Lead Institution

Describe the LI and its commitment to development of a clinical trials network. Provide an overview of the LI including a description of the LI catchment area, the LI organizational capabilities, clinical research portfolio, and the LI overall commitment to the award.

Document the LI's ability to meet the goals of the CTNA including the following:

1. Access to phase 2 and selected phase 3 trials that are appropriate for a community practice setting and meet the needs of the patients served by the proposed Network Affiliates. Describe the LI current trial portfolio and summarize accruals to therapeutic clinical trials for the LI.
2. Access to a clinical trials management system that includes web-based eligibility review and central registration and access to electronic consent forms tailored to meet the language and cultural needs of patients served by the proposed affiliates.

3. Strategies to overcome barriers to clinical trial participation.
4. Safety and quality control monitoring capability.
5. Training for Network Affiliate personnel and opportunities for network personnel to receive CME, CNE, and ACRP maintenance certification.
6. Tumor boards with capability for virtual meeting participation by Network Affiliate personnel.
7. Oversight of the clinical trial scientific aspects and patient safety of the clinical trials available to Network Affiliates.

C. Network Affiliates:

Describe how the Stage 1 Network Affiliate sites were selected and discuss how future Stage 2 Network Affiliate sites will be selected. For the Stage 1 Network Affiliates, do the following:

1. Identify the Stage 1 Network Affiliates and indicate if there are any established affiliation or other existing agreements with the LI.
2. Identify and describe the qualifications and responsibilities of the physician leader who will oversee each Network Affiliate site.
3. Discuss the patient population and geographic region served and document the cancer patient volumes and principal cancers seen for each Network Affiliate.
4. Document that the Network Affiliates have agreed to use the LI IRB or a central IRB.
5. Document that the Network Affiliates have agreed to use the CTMS provided by the LI for protocol access, patient registration, and data monitoring at each Network Affiliate (include information on how the CTMS will be accessed).
6. Document the intent and capability to establish an onsite research pharmacy capability and to recruit a clinical research coordinator responsible for eligibility determination, data collection, and to assist with IRB submissions, industry contracts, and other regulatory documentation.
7. Discuss how Network Affiliate performance metrics will be monitored.

8.2.7. Legal and Contractual Agreements

Provide documentation that the LI and Network Affiliates will use a common IRB.

Provide documentation that the Network Affiliates will allow the data sharing, EMR access, and LI personnel HIPAA business associate status, necessary for the LI personnel to carry out trial monitoring and oversight at the Network Affiliate site. While legal and contractual agreements are not required until an award is recommended by the CPRIT Oversight Committee, both the LI and Network Affiliate Leadership should address plans to enter into these agreements in their letters of support for the CTNA (section 8.2.12).

Certification of these agreements will be required before funding can occur.

8.2.8. Publications/References

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

8.2.9. Budget and Justification

Provide a detailed justification of the budget for the entire proposed period of support for both the LI and each Network Affiliate in Stage 1 (maximum total costs of $600,000 for Years 1 and 2) and Stage 2 (maximum total costs of $900,000 for Years 3 and 4), including salaries and benefits, supplies, and equipment. All clinical trial sites supported by a CPRIT award under this RFA must be in Texas. Salaries can be budgeted for the Network Affiliate for Research Nurse or Coordinator. CPRIT will not reimburse personnel expenses for employees of the LI or Network Affiliate residing outside of Texas.

Note that patient care costs associated with the conduct of a clinical trial are not appropriate for this mechanism.

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 maybe 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 2022 is $200,000; CPRIT FY 2022 is from September 1, 2021, through August 31, 2022. 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.

8.2.10. 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 each Network Affiliate Lead (as required by the online application receipt system). Each biographical sketch must not exceed 5 pages. The NIH biosketch format is recommended.

8.2.11. 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, any Coinvestigators, must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

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

Applicants must provide letters of institutional support, including Network Affiliate's support. A maximum of 4 pages may be provided.

8.2.13. 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 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 if 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. Application Review

Applications will undergo 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 9.3. 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 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 presentand 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. 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 Texas Administrative Code RULE §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 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.

9.3. 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 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.

9.3.1. 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:

Lead Institution: Does the LI document a robust clinical trials program? Will the proposed network expand patient access and geographic proximity to the LI's cancer therapeutic clinical trials? Do plans for the network operation incorporate best practices to ensure timely trial oversight and monitoring to ensure patient safety and the output of high-quality data? Will the LI provide training for network personnel and opportunities for network personnel to receive CME, CNE, and ACRP maintenance certification?

Network Affiliates: Do the Network Affiliates proposed for Stage 1 demonstrate a commitment to providing their patients' access to clinical trials and is the environment and setting of the proposed Network Affiliates adequate to support a clinical trial program? Will the proposed network increase the diversity of the patients with access to the LI sponsored clinical trials? Has a physician leader who will provide overall leadership at the Network Affiliate site been identified?

Network implementation: Do the LI and Network Affiliates agree to use the LI IRB or a central IRB? Do the leadership of the LI and Network Affiliates agree to enter into the legal and contractual agreements necessary to allow the data sharing, EMR access, and LI personnel HIPAA business associate status, necessary for LI personnel to carry out trial monitoring and oversight at the Network Affiliate site? While final legal and contractual agreements are not required until an award is recommended by the CPRIT Oversight Committee, letters of institutional commitment from LI and Network Affiliate Leadership should address their commitments to enter into these agreements.

Principal Investigator: Does the applicant investigator demonstrate the required expertise and experience to lead the network? Has the applicant devoted enough of his or her time (percent effort) to this project?

9.3.2. 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 network? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support?

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	August 30, 2021

Application

Online application opens	October 13, 2021, 7 AM central time
Application due	January 12, 2022, 4 PM central time
Application review	January 2022 to August 2022

Award

Award notification	August 17, 2022
Anticipated start date	August 31, 2022

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 grant 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.

CPRIT recognizes that an LI and/or Network Affiliate may not be considered a public or private institution of higher education or may have an FIDC rate credit that is less than 55%. If that is the case, non-CPRIT funds (eg, federal grants, industry contracts, philanthropic funds, institutional funds, etc) paid to support the clinical trials that are the subject of this award may be used to fulfill the matching funds requirement. CPRIT will also allow the grant recipient to count funds paid for the non-research-related patient care costs toward the matching funds requirement. The grant recipient must submit documentation to CPRIT supporting all matching fund expenses.

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 staffare not able 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: research@cprit.texas.gov

Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT) 22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR) (22.2 AR C/TCR) Observation Report

Report No.	2022-04-26 22.2_AR_C/TCR
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR (22.2 _AR_C/TCR)
Panel Date:	April 26, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR (22.2_AR_C/TCR) meeting. The meeting was chaired by Richard O'Reilly and Margaret Tempero and conducted via videoconference on April 26, 2022.

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: Nineteen (19) applications were discussed, and eleven (11) applications were not discussed
- Panelists: Two (2) panel chairs, twenty-one (21) expert reviewers, and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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) Conflicts of Interest (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

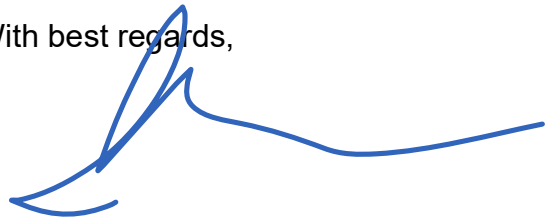
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research Review Panel - Cancer Biology
(22.2_AR_CB)
Observation Report

Report No.	2022-04-27 22.2_AR_CB
Program Name:	Academic Research
Panel Name:	22.2 Academic Research Review Panel - Cancer Biology (22.2 _AR_CB)
Panel Date:	April 27, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research Review Panel - Cancer Biology (22.2_AR_CB) meeting. The meeting was chaired by Peter Jones and conducted via videoconference on April 27, 2022.

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: Thirteen (13) applications were discussed and fifteen (15) applications were not discussed
- Panelists: One (1) panel chair, sixteen (16) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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.

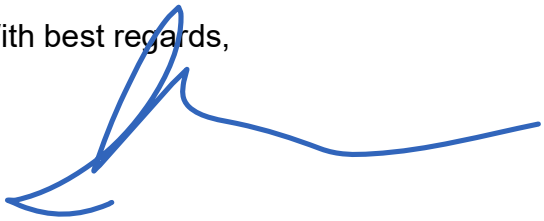
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Basic Cancer Research Panel-1 (22.2_AR_BCR-1)
Observation Report

Report No.	2022-04-28 22.2_AR_BCR-1
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Basic Cancer Research Panel-1 (22.2 _AR_BCR-1)
Panel Date:	April 28, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Basic Cancer Research Panel-1 (22.2_AR_BCR-1) meeting. The meeting was chaired by Steven Fiering and Bart Williams and conducted via videoconference on April 28, 2022.

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: Ten (10) applications were discussed and eight (8) applications were not discussed
- Panelists: Two (2) panel chairs, ten (10) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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) Conflicts of Interest (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

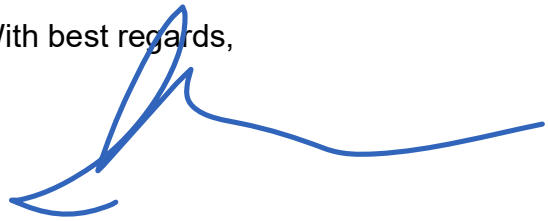
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Imaging Technology and Informatics (22.2_AR_ITI)
Observation Report

Report No.	2022-04-29 22.2_AR_ITI
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Imaging Technology and Informatics (22.2 _AR_ITI)
Panel Date:	April 29, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Imaging Technology and Informatics (22.2_AR_ITI) meeting. The meeting was chaired by Martin Pomper and conducted via videoconference on April 29, 2022.

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: Twelve (12) applications were discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, seventeen (17) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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 six (6) Conflicts of Interest (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

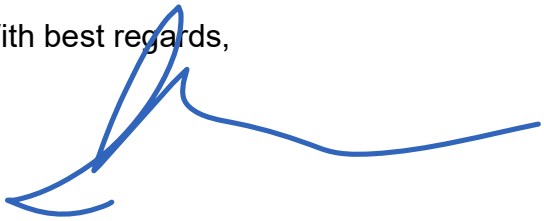
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Basic Cancer Research Panel-2 (22.2_AR_BCR-2)
Observation Report

Report No.	2022-05-05 22.2_AR_BCR-2
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Basic Cancer Research Panel-2 (22.2 _AR_BCR-2)
Panel Date:	May 5, 2022
Report Date:	May 9, 2022

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 22.2 Academic Research - Basic Cancer Research Panel-2 (22.2_AR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via videoconference on May 5, 2022.

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: Ten (10) applications were discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, Fourteen (14) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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.

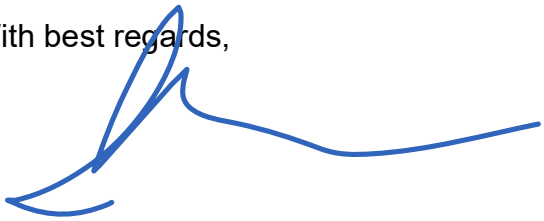
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Scientific Review Council Meeting (22.2_SRC)
Observation Report

Report No.	2022-09-01 22.2_SRC
Program Name:	Academic Research
Panel Name:	22.2 Scientific Review Council Meeting (22.2 _SRC)
Panel Date:	September 1, 2022
Report Date:	September 2, 2022

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 22.2 Scientific Review Council Meeting (22.2_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on September 1, 2022.

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: Thirty-two (32) applications were discussed
- Panelists: One (1) panel chair, and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: One (1)
- 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 was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Three applications from cycle 22.10 REC was added to the aganda on the day of the meeting.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Cycle 22.2

Awards Announced at the September 14, 2022, 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 22.2 include: *Core Facility Support Awards; Clinical Trials Network Award; Early Clinical Investigator Award;* and *High-Impact/High-Risk Research 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	Principal Investigator	Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
RP220553	Wen Jiang	The University of Texas M. D. Anderson Cancer Center	K. Swanson
RP220599	Peter Houghton	The University of Texas Health Science Center at San Antonio	J. Conejo-Garcia
RP220543	Jason Park	The University of Texas Southwestern Medical Center	W. Kast
RP220631	Min Kang	Texas Tech University Health Sciences Center	W. Kast
RP220562	Kenneth Hoyt	The University of Texas at Dallas	K. Zinn
RP220645	Georgios Alexandrakis	The University of Texas at Arlington	A. Chatziioannou
Applications not considered by the PIC or Oversight Committee:			
RP220563	Siyuan Zheng	The University of Texas Health Science Center at San Antonio	J. Conejo-Garcia
RP220622	Aimin Liu	The University of Texas at San Antonio	J. Conejo-Garcia

Application ID	Principal Investigator	Organization	Conflict Noted by Reviewer
RP220557	Steven Berk	Texas Tech University Health Sciences Center	W. Kast
RP220591	Carl Allen	Baylor College of Medicine	W. Kast
RP220642	Gulio Draetta	The University of Texas M. D. Anderson Cancer Center	W. Kast
RP220617	Sherry Yennello	Texas A&M University	D. Mankoff
RP220682	Yichen Ding	The University of Texas at Dallas	A. Chatziioannou;A. Wu
RP220688	Girgis Obaid	The University of Texas at Dallas	K. Zinn

De-Identified Overall Evaluation Scores

Clinical Trials Network Award

Academic Research Cycle 22.2

Application ID	Final Overall Evaluation Score
RP220542*	1.9
ca	4.5

* Recommended for funding

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.

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@health.ucsd.edu

San Diego Branch
UC San Diego School of Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0660
La Jolla, CA 92093-0660

T 858 534 7804
F 858 534 7750

September 1, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

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

Dear Dr. Patel and Mr. Roberts,

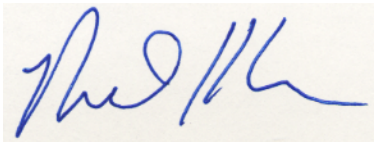
The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Early Clinical Awards, Core Facility Support Awards, Clinical Trials Network Award and High-Impact/Hight Risk Awards.

The SRC met on September 1, 2022 to consider the applications recommended by the peer review panels following their meetings held April 26, 2022 to May 5, 2022.

Recommended funding amounts and the overall evaluation score are stated for each grant application The total amount for the applications recommended is $32,768,514.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing CPRIT's long term goals to achieve a decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products.

Sincerely yours,



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

ID	Award RFA	Score	Application Title	PI	PI Organization	Recommended Budget
RP220582	CFSA	1.0	Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UTSouthwestern Medical Center	Rosen, Michael	The University of Texas Southwestern Medical Center	$4,000,000
RP220646	CFSA	1.8	Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas	Lewis, Michael	Baylor College of Medicine	$3,999,996
RP220544	ECI	1.8	CPRIT Early Clinical Investigator Award-Christopher Alvarez-Breckenridge	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,500,000
RP220606	HIHRRA	1.9	Developing a Novel Optogenetic Recombinase System to Study and Target Metastatic Cancer	Maddipati, Ravikanth	The University of Texas Southwestern Medical Center	$250,000
RP220662	CFSA	1.9	UTHSCSA Cancer Genome Sequencing and Computation Core	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$3,998,688
RP220650	HIHRRA	1.9	Targeting Nitric Oxide Synthase (NOS) Pathway to Remodel Obesity-Induced Tumor Inflammation in Patients With TNBC	Chang, Jenny	The Methodist Hospital Research Institute	$250,000
RP220631	CFSA	1.9	West Texas Pharmacology Core	Kang, Min	Texas Tech University Health Sciences Center	$3,369,480
RP220542	CTNA	1.9	Establish the Accelerating Clinical Oncology Research Network-Texas (ACORN-TX) to Enhance Clinical Trial Access in North and Central Texas	Beg, Muhammad	The University of Texas Southwestern Medical Center	$3,000,000
RP220626	HIHRRA	2.0	A Glia-to-Neuron Conversion for Treating Oral Cancer Pain	Tao, Feng	Texas A&M University System Health Science Center	$237,500

RP220558	HIHRRA	2.0	Novel Covalent Drugs for BCL6	Fast, Walter	The University of Texas at Austin	$249,999
RP220614	HIHRRA	2.0	Understanding the Impact of Immunity on Premalignant Somatic Mosaicism and Cancer Prevention	Zhu, Hao	The University of Texas Southwestern Medical Center	$237,501
RP220666	HIHRRA	2.0	Targeting Tumors and the Tumor Microenvironment With Banana Lectin-Expressing T Cells	McKenna, Katie	Baylor College of Medicine	$250,000
RP220567	HIHRRA	2.0	Fasting-Induced Microbiome Changes and Radioprotection	Piwnica-Worms, Helen	The University of Texas M. D. Anderson Cancer Center	$249,999
RP220645	HIHRRA	2.0	Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy	Alexandrakis, Georgios	The University of Texas at Arlington	$250,000
RP220581	ECI	2.1	Hyperspectral, Quantitative Intraoperative Fluorescence Image-Guided Brain Surgery	Urban, Randall	The University of Texas Medical Branch at Galveston	$1,494,784
RP220599	CFSA	2.3	Texas Pediatric Cancer Testing (TPCT) Core	Houghton, Peter	The University of Texas Health Science Center at San Antonio	$3,935,480
RP220653	HIHRRA	2.3	Novel Modulators of Genomic Instability in Human Cells	Vasquez, Karen	The University of Texas at Austin	$249,932
RP220587	CFSA	2.3	Advanced Protein Therapeutics Core	Maynard, Jennifer	The University of Texas at Austin	$3,995,180
RP220592	HIHRRA	2.4	Restoration of Phagocytosis Function of Glioma-Associated Microglia/Macrophage by Activating QKI-PPARb-RXRa	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	$250,000
RP220600	HIHRRA	2.4	In Vivo Akt Analysis via Chemical Genetics and Nanoparticle-Mediated Probe Delivery	Wang, Degeng	Texas Tech University	$249,999
RP220610	HIHRRA	2.8	Identification of Enhancers of T-Cell Antitumor Activity in PDAC Using CRISPR Activation Screening	Maitra, Anirban	The University of Texas M. D. Anderson Cancer Center	$250,000

RP220553	HIHRRA	2.9	Reversing Aging-Associated Resistance to Cancer Immunotherapy	Jiang, Wen	The University of Texas M. D. Anderson Cancer Center	$249,976
RP220639	HIHRRA	2.9	Targeting NHE6 to Improve Clinical Efficacy of Daratumumab in Myeloma	Yang, Jing	The Methodist Hospital Research Institute	$250,000

CFSA – Core Facility Support Awards
CTNA - Clinical Trials Network Awards
ECI – Early Clinical Investigator Awards
HIHRA – High-Impact/High Risk Awards

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Early Clinical Investigator Award

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-22.2-ECI

Early Clinical Investigator Award

Please also refer to the Instructions for Applicants document, which will be posted on October 13, 2021

Applications for this award mechanism are subject to institutional limits. Applicants are advised to consult with their institution's Office of Research and Sponsored Programs (or equivalent).

Application Receipt Opening Date: October 13, 2021

Application Receipt Closing Date: January 12, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

TABLE OF CONTENTS

RFA VERSION HISTORY

08/30/21 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 $6 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.
- 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 regarding how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- 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
- Expansion of access to innovative clinical trials

2. RATIONALE

The number of highly talented individuals entering a career in clinical investigation is decreasing at a time when the excitement and challenge associated with clinical cancer research has never been greater. The reasons for the decline in cancer clinical investigators are many and include the increased demands on clinical faculty to generate clinical revenue and, as a consequence, limited opportunities for clinical faculty to pursue research; the burden of medical school debt that limits a trainee's options for extending training and pursuing an academic career; and the increasingly complex nature of clinical research requiring specialized training not offered by clinical training programs. Consequently, clinical faculty often do not have the opportunity or experience required to initiate a career as a clinical investigator.

There is concern that this failure of oncology-trained clinicians to pursue careers in patient-oriented research and clinical investigation will seriously impair the ability to translate what has been discovered in the preclinical setting into advances that can benefit patients. Accordingly, there is an urgent need to develop a pipeline of cancer clinicians equipped with the skills and experience necessary to pursue careers in patient-oriented research and capable of leading innovative discovery campaigns through the conduct of clinical trials and **to provide these clinical investigators the protected time from clinical responsibilities that is required to develop and conduct investigator-initiated clinical trials.**

3. OBJECTIVES

The Early Clinical Investigator Award is designed to provide support for the career development of very promising early-career physicians with specialty training relevant to delivery of cancer care, including therapeutic intervention, early detection, and prevention. Candidates are expected to demonstrate the talent, interest, and commitment to ask questions of patients regarding their diseases and their responses to an intervention that would provide new information about the patient's malignancy and, if the intervention worked, why, or more important, if it did not, why not.

The Early Clinical Investigator Award specifically targets physicians with the following:

- **Are within the first 3 years of a faculty appointment at the assistant professor level**
- **Have completed specialty training relevant to cancer care, detection, or prevention and are eligible to be certified by their institution to provide patient care in an oncology-related practice**
- **Plan research that involves the conduct of clinical trials involving a therapeutic intervention, early detection, prevention, symptom control, or behavioral interventions**

The CPRIT Early Clinical Investigator Award will do the following:

- Provide cancer physicians early in their academic career the opportunity to develop clinical research skills and to gain experience in advanced methods and experimental approaches needed to become clinical investigators.
- Provide an opportunity to establish a partnership with a laboratory-based collaborator in order to design and conduct correlative studies needed to interpret the outcome of an interventional trial.
- Provide the protected time from clinical responsibilities required to develop and conduct investigator-initiated clinical trials.
- Increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, capitalizing on basic discoveries and translating them through the conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.

To accomplish these objectives, the CPRIT Early Clinical Investigator Award will provide awards of up to $1,500,000 for up to 5 years to physicians within the first 3 years of a faculty appointment as an assistant professor to acquire additional skills and experience in clinical research and to develop preliminary data that can be used to prepare applications for future research project grants to further both the investigator's career and the CPRIT mission. This award may be used for the following:

- To provide salary support to the candidate
- To support didactic study including enrollment in a degree-granting graduate training program to enhance theoretical and practical skills in design, implementation, and interpretation of data from clinical investigations

- To develop preclinical data and to validate correlative studies with a laboratory-based collaborator
- To support an investigator-initiated clinical trial during the award period

The host institution will be expected to work with each Early Clinical Investigator to design and execute the faculty career development plan consistent with his or her research emphasis. Relevance to cancer and to CPRIT's priority areas are important evaluation criteria for CPRIT funding. CPRIT encourages the participation of all groups underrepresented in biomedical research.

4. INSTITUTIONAL COMMITMENT

CPRIT Early Clinical Investigator Awards are intended to provide clinical faculty who are early in their first faculty position enough time for scholarly activities to develop the knowledge base, experience, and partnership(s) required of a successful clinical investigator. CPRIT recognizes that Early Clinical Investigators will need to commit time to direct patient care in order to hone their clinical expertise and that the time commitment required will vary depending on the nature of the individual's clinical practice and level of prior experience; however, the **institution must commit to limiting the clinical duties of the Early Clinical Investigator to no more than 0.5 FTE for the first three years of the award. In years 4 and 5, the time committed to clinical duties will not be limited in recognition that the Early Clinical Investigator's clinical research program may require an increased clinical involvement.**

A critical component of the Early Clinical Investigator Award is the identification of a mentor (or co-mentors) and the design of a mentoring program that is tailored to the individual's goals and prior experience. The primary mentor should be a clinical and or translational investigator with a strong track record for conducting patient-oriented research. The mentor will be expected to provide an annual progress report that documents progress made toward the goal of independence as a clinical investigator.

5. FUNDING INFORMATION

This award is for **up to 5 years** providing applicants the opportunity to tailor the content and the duration of the award period based upon their individual program. This award is not renewable, although individuals may apply for other future CPRIT funding as appropriate.

Grant funds of up to $1,500,000 (total costs) may be requested. Funding may be used by the Early Clinical Investigator for salary and fringe support (salary up to the CPRIT maximum of $200,000/FTE), for didactic study including enrollment in a degree-granting graduate program, to obtain preclinical data including correlative assay development with a laboratory collaborator, and to support the research project involving an investigator-initiated interventional clinical trial that is a required component of this award.

Applicants are encouraged to design a scholarly training and educational experience that fits the candidate's background and program plan. For example, funds to support didactic study might be emphasized in the first years of the award, and funds to develop correlative assays and to initiate an investigator-initiated clinical trial may be prorated for the later years of the award.

Requests for equipment are not appropriate for this award mechanism except in exceptional circumstances that must be very well justified. Requests for support for faculty mentors are not appropriate for this award. Funds from this award mechanism may not be used to construct or renovate laboratory space.

The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). Candidates are expected to attend CPRIT's conference. CPRIT funds may be used to reimburse registration, travel, and lodging expenses.

Continuation of funding of this award is contingent upon receipt of an annual progress report that documents achievement of the approved training and project milestones (see section 8.2.10).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that provides cancer care and conducts clinical cancer 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.
- **An institution may submit only 2 applications under this RFA during this funding cycle.**
- 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.

- At the time of the application, the candidate must be within 3 years of their first appointment at the assistant professor level or equivalent at an accredited academic institution, research institution, industry, government agency, or private foundation. Exceptions may be granted, if justified, based on a career break due to family obligations or similar circumstances. The candidate must have an MD or DO degree and reside in Texas at the time an award contract is made and for the duration of the appointment.
- The candidate must have oncology subspecialty training or equivalent and be eligible to be certified by their institution to provide patient care in an oncology-related practice. Note: Pathologists and radiologists are eligible for this award.
- Candidates may not hold a Paul Calabresi Career Development Award for Clinical Oncology (K12), a Mentored Clinical Scientist Research Career Development Award (K08) program award, or similar clinical research career development award at the same time as a CPRIT Early Clinical Investigator Award. Individuals who have received a CPRIT First-Time Tenure-Track Faculty Award are not eligible for the Early Clinical Investigator Award.
- Individuals who have received an NIH new investigators award (eg, NIH Director's New Innovator Award or NIH Director's Early Independence Award) are not eligible to apply for the Early Clinical Investigator Award.
- Individuals who have received an NIH R01 or equivalent award (such as DOD Congressionally Directed Medical Research Programs Peer Reviewed Cancer Research Program Career Development Award or a CPRIT Individual Investigator Research Award [targeted or nontargeted]) are not eligible to apply for the Early Clinical Investigator Award.
- Candidates must have identified a mentor who is located at the applicant institution and who agrees to supervise the candidate's career development and research experience.
- 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

An application previously submitted to CPRIT but not funded may be resubmitted once, based on the eligibility criteria of the initial application, and must follow all resubmission guidelines. Note that the resubmission summary should be limited to 1 page, in which the applicant details how the revision has strengthened the application. More than 1 resubmission per application is not permitted. See section 8.2.3.

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 apply. 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 beginning at 7 AM central time on October 13, 2021 and must be submitted by 4 PM central time on January 12, 2022. **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 extenuating circumstances. 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. 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 and the department and/or entity within the nominator's organization where the candidate is appointed.

8.2.2. Institutional Commitment (3 pages)

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 the chair of the candidate's department. The following information should be included in the letter:

- Describe the candidate selection process and the organization's commitment to the candidate's career development as a clinical investigator.
- State the total award amount and duration requested.
- Document that at the time of the Early Clinical Investigator Award contract begins the candidate will be appointed at the assistant professor level (or equivalent) and will be eligible to provide patient care in a cancer-related discipline at the applicant institution.
- Document that a minimum of 50% of the candidate's effort will be available for individual career development and research during the first three years of the Early Clinical Investigator Award. Breach of this requirement will constitute grounds for discontinuation of the award.
- Document how the candidate's mentoring plan and research experience were developed and how the institution will oversee the candidate's development as clinical investigator.
- Provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations and leveraging the institution's unique strengths will foster the candidate's career trajectory.

8.2.3. Resubmission Summary (1 page)

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. For resubmitted applications, candidates are allowed to be within the first 5 years of a faculty appointment at the assistant professor level.

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.

8.2.4. 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. Goals and Objectives (1,200 characters per goal and per objective)

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. **This section and the following section (8.2.6) must be prepared by the candidate.**

8.2.6. Candidate Information and Career Development Plan (10 pages)

Candidate Background

- Describe the candidate's commitment to an academic career in patient-oriented research.
- Describe the candidate's prior training and how it relates to the goals and long-term career plans of the candidate.
- Describe all the candidate's clinical and other professional responsibilities/activities in the grantee institution beyond the commitment to career development and research and elsewhere and describe their relationship to the proposed activities on this award.
- Describe the candidate's research efforts to this point, including any publications, prior research interests, and experience.

Career Development Plan

- Describe the candidate's mentored research development plan that includes intent to implement an investigator-initiated clinical trial by Year 3 of the award. Include a timeline chart to illustrate this plan.
- Describe any didactic and research experience(s) designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals.
- Demonstrate that the candidate has received training or will participate in courses such as biostatistics, data management, epidemiology, study design, hypothesis development, and drug development including FDA regulatory policies, etc, as well as the legal and ethical issues associated with research on human subjects. **Candidates are encouraged to pursue as part of the Early Clinical Investigator Award an advanced degree-granting program to gain this knowledge**. In addition, candidates may wish to design opportunities to gain experience in clinical investigations as part of an internship or similar arrangement with a pharmaceutical organization.

Research Plan

- Describe a research plan that will lead to the design and implementation of an investigator-initiated clinical trial.
- While the focus of the Early Clinical Investigator Award is on patient-oriented research, complementary laboratory-based research directly related to the proposed patient-oriented research project may be proposed in the application and is strongly encouraged, thereby providing an opportunity to obtain preclinical data and to develop and validate any proposed correlative assays with a laboratory-based collaborator. If correlative studies are proposed, a qualified collaborator who is able and willing to participate in the design and conduct of the correlative studies needed should be identified and, if not already identified as a co-mentor, provide a letter of intent to collaborate and a biosketch.

Clinical Trial Plan

- Describe the planned investigator-initiated clinical trial protocol that the candidate will lead as the Principal Investigator, including metrics for success, and a timeline to initiation of the trial within the first 2 years of the award.

- The description should include rationale, objectives, end points, correlative studies, and statistical considerations. Trials that incorporate corresponding translational research are strongly encouraged.
- Applicants are advised to pay close attention to careful documentation of the trial's feasibility and inclusion of robust statistical considerations.

8.2.7. Mentor, Co-mentor (4-page description)

Name a primary mentor who, together with the candidate, is responsible for planning, directing, monitoring, and executing the proposed program. The primary mentor is required to be an experienced clinical investigator. Co-mentors as appropriate to the goals of the program are encouraged.

Include a statement from the mentor providing (1) information on his/her background as a clinical investigator and previous experience as a mentor, (2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period, (3) a plan for career progression for the candidate to move from the mentored stage of his/her career to independent research investigator status during the project period of the award, and (4) a plan for monitoring the candidate's research, publications, and progress over the course of the award.

Similar information must be provided by any co-mentor. The mentor and any co-mentor(s) should clearly describe how they will coordinate mentoring of the candidate.

The primary mentor must agree to provide annual evaluations of the candidate's progress in the annual progress report.

8.2.8. Mentor, Co-mentor Biographical Sketches (5 pages each)

Biosketches that include current and past funding for the mentor and all co-mentors must be provided. Biosketches should also include education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 5 pages.

8.2.9. Biographical Sketches of Collaborators (5 pages each)

Applicants may provide up to 2 additional biographical sketches for collaborators or key personnel. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

8.2.10. Timeline (1 page)

Provide an outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. **Note that the progress report at the completion of Year 2 of this award must include an investigator-initiated clinical trial protocol and a detailed timeline for implementation.**

If the application is approved for funding, this section will be included in the award contract and will be used to monitor progress. Failure to demonstrate robust progress may result in early termination of the grant award. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.11. Current and Pending Support

State the funding source, duration, and title of all current and pending financial support including any research awards 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.

8.2.12. Letters of Recommendation

Provide 2 letters of recommendation from individuals in addition to the mentor and co-mentor who can detail the candidate's academic accomplishments, potential as a clinical investigator, and ability to make a significant contribution to the field of cancer research.

8.2.13. Research Environment (1 page)

Clearly and concisely describe the research environment available to support the candidate's research program as well as access to clinical facilities and patients, core facilities, didactic programs, and collaborative opportunities.

8.2.14. Collaborator Support and/or Other Certification (2 pages)

Applicants may provide letters of collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 2 pages may be provided

8.2.15. 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 do not meet the eligibility requirements listed above will be administratively withdrawn 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 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. Review Process

All applications will undergo 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 9.3. 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 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, Texas Administrative Code, Title 25, chapters 701 to 703.

9.2. 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, Texas Administrative Code, Title 25, chapters 701 to 703.

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.

9.3. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for development as a clinical investigator. **Also of critical importance is the strength**

of the institutional commitment to the candidate's career development and the track record of the candidate's mentor(s).

Review criteria will focus on the overall impression of the candidate and the proposed career development plan, the institution's commitment to the candidate's career development as a clinical investigator, and his or her long-term potential to have an 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 training as a clinician in a cancer discipline? Does the candidate show exceptional potential for making an impact on cancer research in the future?

Institutional commitment and mentorship plan: Will the candidate have enough time and support to develop as a clinical investigator? Is the mentor(s) and mentorship plan well developed and tailored to guide the candidate to achieve the candidate's career goals?

Relevance of Candidate's career and clinical trials plan: Is the proposed area of focus likely to have a significant impact on reducing the burden of cancer in the near term?

Letters of Recommendation: Do the letters of recommendation detail the candidate's academic and clinical accomplishments, potential for innovation as a clinical investigator, 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 including access to patients to support the candidate's development? Is there evidence of strong institutional support? Will the candidate's administrative/clinical responsibilities be sufficiently limited so that he or she can focus on growing his or her research? Has the institution identified a mentor who will collaborate with the candidate in the design and oversight of a faculty career development plan for the candidate? If correlative studies are proposed, is a qualified collaborator who is able and willing to participate in the design and conduct of the correlative studies needed identified.

10. KEY DATES

RFA

RFA release	August 30, 2021

Application

Online application opens	October 13, 2021, 7 AM central time
Application due	January 12, 2022, 4 PM central time
Application review	January 2022 to August 2022

Award

Award notification	August 17, 2022
Anticipated start date	August 31, 2022

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 Texas Administrative Code, Title 25, chapters 701 to 703.

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 Texas Administrative Code, Title 25, chapters 701 to 703.

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, Texas Administrative Code, Title 25, chapters 701 to 703.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals outlined in section 8.2.5 and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. **CPRIT's Academic Research Program staff reviews the progress reports, and continuation of funding is contingent upon demonstration of progress and achievement of the goals set forth in section 8.2.5.** 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, Texas Administrative Code, Title 25, chapters 701 to 703, 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: research@cprit.texas.gov
Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT) 22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR) (22.2 AR C/TCR) Observation Report

Report No.	2022-04-26 22.2_AR_C/TCR
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR (22.2 _AR_C/TCR)
Panel Date:	April 26, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR (22.2_AR_C/TCR) meeting. The meeting was chaired by Richard O'Reilly and Margaret Tempero and conducted via videoconference on April 26, 2022.

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: Nineteen (19) applications were discussed, and eleven (11) applications were not discussed
- Panelists: Two (2) panel chairs, twenty-one (21) expert reviewers, and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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) Conflicts of Interest (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

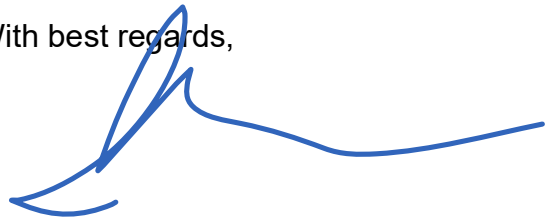
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research Review Panel - Cancer Biology
(22.2_AR_CB)
Observation Report

Report No.	2022-04-27 22.2_AR_CB
Program Name:	Academic Research
Panel Name:	22.2 Academic Research Review Panel - Cancer Biology (22.2 _AR_CB)
Panel Date:	April 27, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research Review Panel - Cancer Biology (22.2_AR_CB) meeting. The meeting was chaired by Peter Jones and conducted via videoconference on April 27, 2022.

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: Thirteen (13) applications were discussed and fifteen (15) applications were not discussed
- Panelists: One (1) panel chair, sixteen (16) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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.

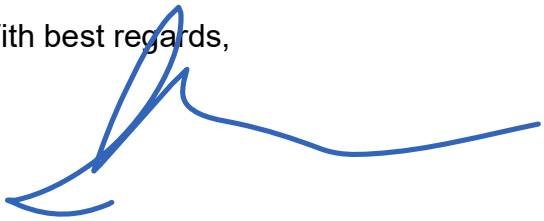
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Basic Cancer Research Panel-1 (22.2_AR_BCR-1)
Observation Report

Report No.	2022-04-28 22.2_AR_BCR-1
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Basic Cancer Research Panel-1 (22.2 _AR_BCR-1)
Panel Date:	April 28, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Basic Cancer Research Panel-1 (22.2_AR_BCR-1) meeting. The meeting was chaired by Steven Fiering and Bart Williams and conducted via videoconference on April 28, 2022.

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: Ten (10) applications were discussed and eight (8) applications were not discussed
- Panelists: Two (2) panel chairs, ten (10) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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) Conflicts of Interest (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

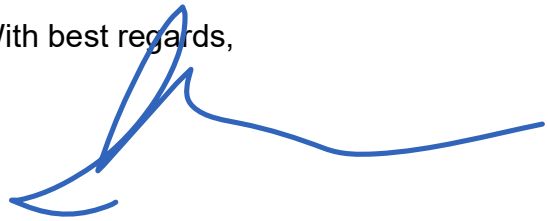
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Imaging Technology and Informatics (22.2_AR_ITI)
Observation Report

Report No.	2022-04-29 22.2_AR_ITI
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Imaging Technology and Informatics (22.2 _AR_ITI)
Panel Date:	April 29, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Imaging Technology and Informatics (22.2_AR_ITI) meeting. The meeting was chaired by Martin Pomper and conducted via videoconference on April 29, 2022.

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: Twelve (12) applications were discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, seventeen (17) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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 six (6) Conflicts of Interest (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

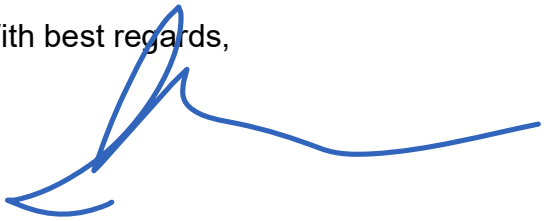
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Basic Cancer Research Panel-2 (22.2_AR_BCR-2)
Observation Report

Report No.	2022-05-05 22.2_AR_BCR-2
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Basic Cancer Research Panel-2 (22.2 _AR_BCR-2)
Panel Date:	May 5, 2022
Report Date:	May 9, 2022

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 22.2 Academic Research - Basic Cancer Research Panel-2 (22.2_AR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via videoconference on May 5, 2022.

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: Ten (10) applications were discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, Fourteen (14) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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.

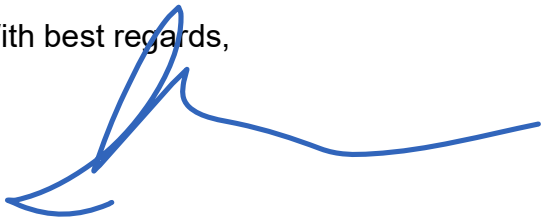
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Scientific Review Council Meeting (22.2_SRC)
Observation Report

Report No.	2022-09-01 22.2_SRC
Program Name:	Academic Research
Panel Name:	22.2 Scientific Review Council Meeting (22.2 _SRC)
Panel Date:	September 1, 2022
Report Date:	September 2, 2022

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 22.2 Scientific Review Council Meeting (22.2_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on September 1, 2022.

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: Thirty-two (32) applications were discussed
- Panelists: One (1) panel chair, and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: One (1)
- 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 was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Three applications from cycle 22.10 REC was added to the aganda on the day of the meeting.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Cycle 22.2

Awards Announced at the September 14, 2022, 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 22.2 include: *Core Facility Support Awards; Clinical Trials Network Award; Early Clinical Investigator Award;* and *High-Impact/High-Risk Research 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	Principal Investigator	Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
RP220553	Wen Jiang	The University of Texas M. D. Anderson Cancer Center	K. Swanson
RP220599	Peter Houghton	The University of Texas Health Science Center at San Antonio	J. Conejo-Garcia
RP220543	Jason Park	The University of Texas Southwestern Medical Center	W. Kast
RP220631	Min Kang	Texas Tech University Health Sciences Center	W. Kast
RP220562	Kenneth Hoyt	The University of Texas at Dallas	K. Zinn
RP220645	Georgios Alexandrakis	The University of Texas at Arlington	A. Chatziioannou
Applications not considered by the PIC or Oversight Committee:			
RP220563	Siyuan Zheng	The University of Texas Health Science Center at San Antonio	J. Conejo-Garcia
RP220622	Aimin Liu	The University of Texas at San Antonio	J. Conejo-Garcia

Application ID	Principal Investigator	Organization	Conflict Noted by Reviewer
RP220557	Steven Berk	Texas Tech University Health Sciences Center	W. Kast
RP220591	Carl Allen	Baylor College of Medicine	W. Kast
RP220642	Gulio Draetta	The University of Texas M. D. Anderson Cancer Center	W. Kast
RP220617	Sherry Yennello	Texas A&M University	D. Mankoff
RP220682	Yichen Ding	The University of Texas at Dallas	A. Chatziioannou;A. Wu
RP220688	Girgis Obaid	The University of Texas at Dallas	K. Zinn

De-Identified Overall Evaluation Scores

Early Clinical Investigator Award

Academic Research Cycle 22.2

Application ID	Final Overall Evaluation Score
RP220544*	1.8
RP220581*	2.1
Da	4.0
Db	4.1
Dc	4.3
Dd	4.5

* Recommended for funding

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.

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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September 1, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

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

Dear Dr. Patel and Mr. Roberts,

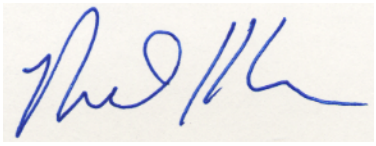
The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Early Clinical Awards, Core Facility Support Awards, Clinical Trials Network Award and High-Impact/Hight Risk Awards.

The SRC met on September 1, 2022 to consider the applications recommended by the peer review panels following their meetings held April 26, 2022 to May 5, 2022.

Recommended funding amounts and the overall evaluation score are stated for each grant application The total amount for the applications recommended is $32,768,514.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing CPRIT's long term goals to achieve a decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products.

Sincerely yours,



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

ID	Award RFA	Score	Application Title	PI	PI Organization	Recommended Budget
RP220582	CFSA	1.0	Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UTSouthwestern Medical Center	Rosen, Michael	The University of Texas Southwestern Medical Center	$4,000,000
RP220646	CFSA	1.8	Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas	Lewis, Michael	Baylor College of Medicine	$3,999,996
RP220544	ECI	1.8	CPRIT Early Clinical Investigator Award-Christopher Alvarez-Breckenridge	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,500,000
RP220606	HIHRRA	1.9	Developing a Novel Optogenetic Recombinase System to Study and Target Metastatic Cancer	Maddipati, Ravikanth	The University of Texas Southwestern Medical Center	$250,000
RP220662	CFSA	1.9	UTHSCSA Cancer Genome Sequencing and Computation Core	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$3,998,688
RP220650	HIHRRA	1.9	Targeting Nitric Oxide Synthase (NOS) Pathway to Remodel Obesity-Induced Tumor Inflammation in Patients With TNBC	Chang, Jenny	The Methodist Hospital Research Institute	$250,000
RP220631	CFSA	1.9	West Texas Pharmacology Core	Kang, Min	Texas Tech University Health Sciences Center	$3,369,480
RP220542	CTNA	1.9	Establish the Accelerating Clinical Oncology Research Network-Texas (ACORN-TX) to Enhance Clinical Trial Access in North and Central Texas	Beg, Muhammad	The University of Texas Southwestern Medical Center	$3,000,000
RP220626	HIHRRA	2.0	A Glia-to-Neuron Conversion for Treating Oral Cancer Pain	Tao, Feng	Texas A&M University System Health Science Center	$237,500

RP220558	HIHRRA	2.0	Novel Covalent Drugs for BCL6	Fast, Walter	The University of Texas at Austin	$249,999
RP220614	HIHRRA	2.0	Understanding the Impact of Immunity on Premalignant Somatic Mosaicism and Cancer Prevention	Zhu, Hao	The University of Texas Southwestern Medical Center	$237,501
RP220666	HIHRRA	2.0	Targeting Tumors and the Tumor Microenvironment With Banana Lectin-Expressing T Cells	McKenna, Katie	Baylor College of Medicine	$250,000
RP220567	HIHRRA	2.0	Fasting-Induced Microbiome Changes and Radioprotection	Piwnica-Worms, Helen	The University of Texas M. D. Anderson Cancer Center	$249,999
RP220645	HIHRRA	2.0	Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy	Alexandrakis, Georgios	The University of Texas at Arlington	$250,000
RP220581	ECI	2.1	Hyperspectral, Quantitative Intraoperative Fluorescence Image-Guided Brain Surgery	Urban, Randall	The University of Texas Medical Branch at Galveston	$1,494,784
RP220599	CFSA	2.3	Texas Pediatric Cancer Testing (TPCT) Core	Houghton, Peter	The University of Texas Health Science Center at San Antonio	$3,935,480
RP220653	HIHRRA	2.3	Novel Modulators of Genomic Instability in Human Cells	Vasquez, Karen	The University of Texas at Austin	$249,932
RP220587	CFSA	2.3	Advanced Protein Therapeutics Core	Maynard, Jennifer	The University of Texas at Austin	$3,995,180
RP220592	HIHRRA	2.4	Restoration of Phagocytosis Function of Glioma-Associated Microglia/Macrophage by Activating QKI-PPARb-RXRa	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	$250,000
RP220600	HIHRRA	2.4	In Vivo Akt Analysis via Chemical Genetics and Nanoparticle-Mediated Probe Delivery	Wang, Degeng	Texas Tech University	$249,999
RP220610	HIHRRA	2.8	Identification of Enhancers of T-Cell Antitumor Activity in PDAC Using CRISPR Activation Screening	Maitra, Anirban	The University of Texas M. D. Anderson Cancer Center	$250,000

RP220553	HIHRRA	2.9	Reversing Aging-Associated Resistance to Cancer Immunotherapy	Jiang, Wen	The University of Texas M. D. Anderson Cancer Center	$249,976
RP220639	HIHRRA	2.9	Targeting NHE6 to Improve Clinical Efficacy of Daratumumab in Myeloma	Yang, Jing	The Methodist Hospital Research Institute	$250,000

CFSA – Core Facility Support Awards
CTNA - Clinical Trials Network Awards
ECI – Early Clinical Investigator Awards
HIHRA – High-Impact/High Risk Awards

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
High-Impact/High-Risk Research Awards

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-22.2-HIHR

High-Impact/High-Risk Research Awards

Please also refer to the Instructions for Applicants document, which will be posted October 13, 2021

Applications for this award mechanism are subject to institutional limits. Applicants are advised to consult with their institution's Office of Research and Sponsored Programs (or equivalent).

Application Receipt Opening Date: October 13, 2021

Application Receipt Closing Date: January 12, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

RFA release 08/30/2021

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 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.
- 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
- 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
- Expansion of access to innovative clinical trials

2. RATIONALE

CPRIT High-Impact/High-Risk (HIHR) Research Awards seek to provide short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Because HIHR Research Awards are designed to support new ideas, preliminary data are not required. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. The HIHR Research Awards are expected to provide the foundation for individual or multiple investigator awards upon completion. Applicants must explain why more conventional sources of support are not available for the proposed research and how short-term funding will lead to strong applications for additional support.

Applications that might be described as "mini-R01s" will not be competitive. **The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data. There should be reasons for the idea to be plausible, but CPRIT acknowledges that most of the selected projects will ultimately fail to meet their primary goals. The rare proposals that succeed will be of sufficient importance to justify this program.** Applications may address any research topic related to cancer biology, causation, prevention, detection, screening, treatment, or survivorship.

3. RESEARCH OBJECTIVES

Areas of interest include laboratory research, translational studies, and population-based and/or clinical investigations. In that cancers arise from a large number of derangements of basic molecular and cellular functions, which, 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 will be an important criterion for evaluation of projects for funding by CPRIT (section 8.3.1). 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 total of $250,000 for a period of up to 24 months (2 years), inclusive of both direct and indirect costs. Because of the nature of this funding mechanism, renewal applications will not be accepted. Follow-on applications will not be funded until the initial HIHR Award grant period has passed. Award funds may be used to pay for salary and benefits, research supplies, equipment, and clinical costs. *Requests for funds for travel to scientific meetings other than the CPRIT biennial conference are not appropriate for this funding mechanism, nor are requests for funds to support construction and/or renovation.* 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 also eligible for funding under this award mechanism.
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent and reside in Texas for the period of the time that the research that is the subject of the grant application is conducted.
- A PI may submit only 1 new or resubmission application under this RFA during this funding cycle. The PI must commit a minimum 5% level of effort throughout the entire award period.
- One Coinvestigator may be included. An individual may serve as a Coinvestigator in more than 1 application but should ensure that he or she could dedicate adequate time and effort should more than 1 application be funded. The Coinvestigator must reside in Texas for the period of the time that the research that is the subject of the grant application is conducted.
- 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. Collaborators should have specific and well-defined roles. 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 individual may serve as a PI on no more than 3 active Academic Research grants. Recruitment Grants and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers project leaders on a MIRA award 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 8/31/2022).
- 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 institution or organization 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 10 and section 11. 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.

7. RESPONDING TO THIS RFA

7.1. 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. 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. Please refer to the *Instructions for Applicants (IFA)* document for the instructions on adding Key Personnel to an application. The *IFA* document will be available when the application receipts system opens.

Applications will be accepted beginning at 7 AM central time on October 13, 2021and must be submitted by 4 PM central time on January 12, 2022. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

7.1.1. Submission Deadline Extension

The submission deadline may be extended upon a showing of extenuating circumstances. 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.

7.2. 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 that do not meet the eligibility requirements listed in section 5 will be administratively withdrawn without review.

7.2.1. Abstract and Significance (5,000 characters)

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 the field of cancer research or on the care of patients with cancer. Summarize how the proposed research creates new paradigms or challenges existing ones.

7.2.2. 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 prevention research, early diagnosis, 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 8.1) in evaluating the significance and impact of the proposed work.

7.2.3. 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 if the award is made.

7.2.4. 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.

7.2.5. Resubmission Summary (1 page)

An application previously submitted to CPRIT but not funded may be resubmitted **once** after careful consideration of the reasons for lack of prior success. 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.

7.2.6. Research Plan (4 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed. Preliminary data are not required, but strong reasoning and literature support will obviously enhance the application.

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.

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

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

7.2.8. Publications/References

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

7.2.9. Budget and Justification

Provide a compelling 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. Applications requesting more than $250,000 (total costs) over a maximum period of 24 months (2 years) will be administratively withdrawn.

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

- Major equipment purchases are discouraged for this funding mechanism. 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 be reimbursed from a CPRIT award 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.
- The PI must commit a minimum 5% level of effort throughout the entire award period.

7.2.10. 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 Coinvestigator (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.

7.2.11. Current and Pending Support

State 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, any additional investigator must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

7.2.12. Institutional/Collaborator Support and/or Other Certification (2 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 2 pages may be provided.

7.2.13. 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.

7.2.14. Institutional Limits

In order to ensure timely and high-quality review of the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, CPRIT is imposing a limit of 5 applications from an academic research institution and 1 each from public or private companies on the number of HIHR Research Award applications that may be submitted by an institution during this review cycle.

The limit on the number of applications may seem restrictive, but experience indicates that truly innovative ideas that are appropriate for this award mechanism are uncommon. CPRIT expects institutions to initiate an internal review process and only authorize submission of the

appropriate number of applications that have been rigorously judged to be responsive to this RFA.

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.

7.3. 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 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.

8. APPLICATION REVIEW

8.1. Review Process Overview

All eligible applications will be evaluated using a 2-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council (SRC). 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 below. 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 SRC based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by the SRC 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.

8.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, SRC 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 SRC 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, Texas Administrative Code, Title 25, chapters 701 to 703.

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 SRC 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. The prohibition on communication does not apply to the time period prior to the opening of CARS. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

8.3. Review Criteria

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.

8.3.1. 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: Is the application clearly responsive to the RFA and specifically to the HIHR Research Award mechanism? What is the innovative potential of the project? 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? Responsive applications will be highly speculative or exploratory; they need not be based on preliminary data but must have the potential for high scientific payoff because of exceptionally promising ideas.

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 a sound 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, expertise, experience, and accomplishments 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? This will be an important criterion for evaluation of projects for CPRIT support.

8.3.2. 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: If vertebrate animals and/or human biological samples are included in the proposed research, is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed? Note that certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget and Duration: Are the budget and the duration appropriate for the proposed work?

9. KEY DATES

RFA

RFA release	August 30, 2021

Application

Online application opens	October 13, 2021, 7 AM central time
Application due	January 12, 2022, 4 PM central time
Application review	January 2022 to August 2022

Award

Award notification	August 17, 2022
Anticipated start date	August 31, 2022

10. 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 Texas Administrative Code, Title 25, chapters 701 to 703.

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 Texas Administrative Code, Title 25, chapters 701 to 703.

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, Texas Administrative Code, Title 25, chapters 701 to 703.

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.

11. 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, Texas Administrative Code, Title 25, chapters 701 to 703 for specific requirements regarding the demonstration of available funding.

12. CONTACT INFORMATION

12.1. 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

12.2. 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 Program Manager for Academic Research.

Tel: 512-305-8491
Email: research@cprit.texas.gov
Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT) 22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR) (22.2 AR C/TCR) Observation Report

Report No.	2022-04-26 22.2_AR_C/TCR
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR (22.2 _AR_C/TCR)
Panel Date:	April 26, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Clinical and Translational Cancer Research (C/TCR (22.2_AR_C/TCR) meeting. The meeting was chaired by Richard O'Reilly and Margaret Tempero and conducted via videoconference on April 26, 2022.

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: Nineteen (19) applications were discussed, and eleven (11) applications were not discussed
- Panelists: Two (2) panel chairs, twenty-one (21) expert reviewers, and three (3) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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) Conflicts of Interest (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

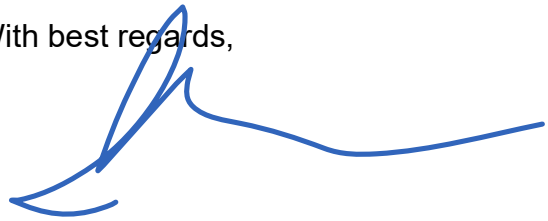
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research Review Panel - Cancer Biology
(22.2_AR_CB)
Observation Report

Report No.	2022-04-27 22.2_AR_CB
Program Name:	Academic Research
Panel Name:	22.2 Academic Research Review Panel - Cancer Biology (22.2 _AR_CB)
Panel Date:	April 27, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research Review Panel - Cancer Biology (22.2_AR_CB) meeting. The meeting was chaired by Peter Jones and conducted via videoconference on April 27, 2022.

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: Thirteen (13) applications were discussed and fifteen (15) applications were not discussed
- Panelists: One (1) panel chair, sixteen (16) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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.

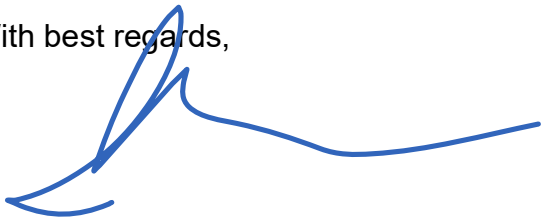
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Basic Cancer Research Panel-1 (22.2_AR_BCR-1)
Observation Report

Report No.	2022-04-28 22.2_AR_BCR-1
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Basic Cancer Research Panel-1 (22.2 _AR_BCR-1)
Panel Date:	April 28, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Basic Cancer Research Panel-1 (22.2_AR_BCR-1) meeting. The meeting was chaired by Steven Fiering and Bart Williams and conducted via videoconference on April 28, 2022.

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: Ten (10) applications were discussed and eight (8) applications were not discussed
- Panelists: Two (2) panel chairs, ten (10) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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) Conflicts of Interest (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

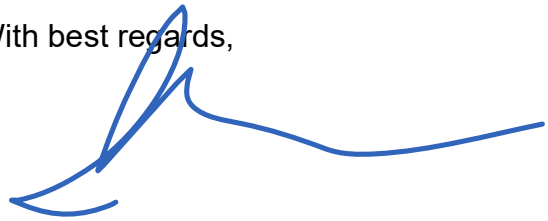
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Imaging Technology and Informatics (22.2_AR_ITI)
Observation Report

Report No.	2022-04-29 22.2_AR_ITI
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Imaging Technology and Informatics (22.2 _AR_ITI)
Panel Date:	April 29, 2022
Report Date:	May 3, 2022

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 22.2 Academic Research - Imaging Technology and Informatics (22.2_AR_ITI) meeting. The meeting was chaired by Martin Pomper and conducted via videoconference on April 29, 2022.

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: Twelve (12) applications were discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, seventeen (17) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- 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 six (6) Conflicts of Interest (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

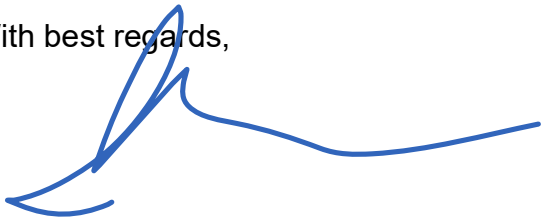
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Academic Research - Basic Cancer Research Panel-2 (22.2_AR_BCR-2)
Observation Report

Report No.	2022-05-05 22.2_AR_BCR-2
Program Name:	Academic Research
Panel Name:	22.2 Academic Research - Basic Cancer Research Panel-2 (22.2 _AR_BCR-2)
Panel Date:	May 5, 2022
Report Date:	May 9, 2022

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 22.2 Academic Research - Basic Cancer Research Panel-2 (22.2_AR_BCR-2) meeting. The meeting was chaired by Carol Prives and conducted via videoconference on May 5, 2022.

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: Ten (10) applications were discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, Fourteen (14) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4)
- 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 no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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.

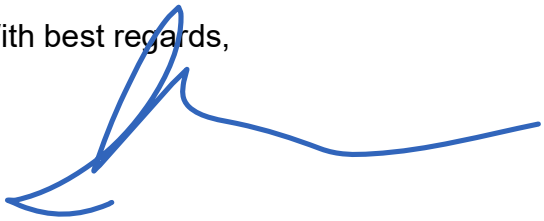
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Scientific Review Council Meeting (22.2_SRC)
Observation Report

Report No.	2022-09-01 22.2_SRC
Program Name:	Academic Research
Panel Name:	22.2 Scientific Review Council Meeting (22.2 _SRC)
Panel Date:	September 1, 2022
Report Date:	September 2, 2022

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 22.2 Scientific Review Council Meeting (22.2_SRC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on September 1, 2022.

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: Thirty-two (32) applications were discussed
- Panelists: One (1) panel chair, and six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: One (1)
- 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 was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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. Three applications from cycle 22.10 REC was added to the aganda on the day of the meeting.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Cycle 22.2

Awards Announced at the September 14, 2022, 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 22.2 include: *Core Facility Support Awards; Clinical Trials Network Award; Early Clinical Investigator Award;* and *High-Impact/High-Risk Research 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	Principal Investigator	Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
RP220553	Wen Jiang	The University of Texas M. D. Anderson Cancer Center	K. Swanson
RP220599	Peter Houghton	The University of Texas Health Science Center at San Antonio	J. Conejo-Garcia
RP220543	Jason Park	The University of Texas Southwestern Medical Center	W. Kast
RP220631	Min Kang	Texas Tech University Health Sciences Center	W. Kast
RP220562	Kenneth Hoyt	The University of Texas at Dallas	K. Zinn
RP220645	Georgios Alexandrakis	The University of Texas at Arlington	A. Chatziioannou
Applications not considered by the PIC or Oversight Committee:			
RP220563	Siyuan Zheng	The University of Texas Health Science Center at San Antonio	J. Conejo-Garcia
RP220622	Aimin Liu	The University of Texas at San Antonio	J. Conejo-Garcia

Application ID	Principal Investigator	Organization	Conflict Noted by Reviewer
RP220557	Steven Berk	Texas Tech University Health Sciences Center	W. Kast
RP220591	Carl Allen	Baylor College of Medicine	W. Kast
RP220642	Gulio Draetta	The University of Texas M. D. Anderson Cancer Center	W. Kast
RP220617	Sherry Yennello	Texas A&M University	D. Mankoff
RP220682	Yichen Ding	The University of Texas at Dallas	A. Chatziioannou;A. Wu
RP220688	Girgis Obaid	The University of Texas at Dallas	K. Zinn

De-Identified Overall Evaluation Scores

High-Impact/High-Risk Research Awards

Academic Research Cycle 22.2

Application ID	Final Overall Evaluation Score
RP220606*	1.9
RP220650*	1.9
RP220626*	2.0
RP220558*	2.0
RP220614*	2.0
RP220666*	2.0
RP220567*	2.0
RP220645*	2.0
RP220653*	2.3
RP220592*	2.4
RP220600*	2.4
RP220610*	2.8
RP220553*	2.9
RP220639*	2.9
Ea	3.1
Eb	3.3
Ec	3.3
Ed	3.5
Ee	3.3
Ef	3.6
Eg	3.7
Eh	3.8
Ei	3.8
Ej	4.0
Ek	4.0
El	4.0
Em	4.2
En	4.2
Eo	4.3
Ep	4.3
Eq	4.3
Er	4.3
Es	4.3
Et	4.3
Eu	4.3
Ev	4.3
Ew	4.4
Ex	4.5

* Recommended for funding

Application ID	Final Overall Evaluation Score
Ey	4.6
Ez	4.6
Fa	4.7
Fb	4.7
Fc	4.7
Fd	4.7
Fe	4.7
Ff	4.7
Fg	4.7
Fh	4.7
Fi	4.7
Fj	4.7
Fk	4.8
Fl	4.8
Fm	4.9
Fn	4.9
Fo	5.0
Fp	5.0
Fq	5.0
Fr	5.0
Fs	5.0
Ft	5.0
Fu	5.0
Fv	5.0
Fw	5.0
Fx	5.0
Fy	5.0
Fz	5.0
Ga	5.0
Gb	5.0
Gc	5.0
Gd	5.1
Ge	5.3
Gf	5.3
Gg	5.3
Gh	5.4
Gi	5.5
Gj	5.7
Gk	5.7
Gl	5.7
Gm	6.0

* Recommended for funding

Application ID	Final Overall Evaluation Score
Gn	6.0
Go	6.0
Gp	6.0
Gq	6.0
Gr	6.3
Gs	6.3
Gt	6.3
Gu	6.3
Gv	6.7
Gw	7.2

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.

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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September 1, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

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

Dear Dr. Patel and Mr. Roberts,

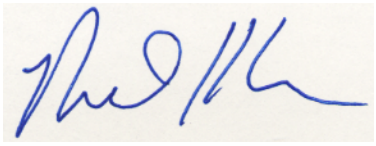
The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for Early Clinical Awards, Core Facility Support Awards, Clinical Trials Network Award and High-Impact/Hight Risk Awards.

The SRC met on September 1, 2022 to consider the applications recommended by the peer review panels following their meetings held April 26, 2022 to May 5, 2022.

Recommended funding amounts and the overall evaluation score are stated for each grant application The total amount for the applications recommended is $32,768,514.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing CPRIT's long term goals to achieve a decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products.

Sincerely yours,



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

ID	Award RFA	Score	Application Title	PI	PI Organization	Recommended Budget
RP220582	CFSA	1.0	Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UTSouthwestern Medical Center	Rosen, Michael	The University of Texas Southwestern Medical Center	$4,000,000
RP220646	CFSA	1.8	Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas	Lewis, Michael	Baylor College of Medicine	$3,999,996
RP220544	ECI	1.8	CPRIT Early Clinical Investigator Award-Christopher Alvarez-Breckenridge	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,500,000
RP220606	HIHRRA	1.9	Developing a Novel Optogenetic Recombinase System to Study and Target Metastatic Cancer	Maddipati, Ravikanth	The University of Texas Southwestern Medical Center	$250,000
RP220662	CFSA	1.9	UTHSCSA Cancer Genome Sequencing and Computation Core	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$3,998,688
RP220650	HIHRRA	1.9	Targeting Nitric Oxide Synthase (NOS) Pathway to Remodel Obesity-Induced Tumor Inflammation in Patients With TNBC	Chang, Jenny	The Methodist Hospital Research Institute	$250,000
RP220631	CFSA	1.9	West Texas Pharmacology Core	Kang, Min	Texas Tech University Health Sciences Center	$3,369,480
RP220542	CTNA	1.9	Establish the Accelerating Clinical Oncology Research Network-Texas (ACORN-TX) to Enhance Clinical Trial Access in North and Central Texas	Beg, Muhammad	The University of Texas Southwestern Medical Center	$3,000,000
RP220626	HIHRRA	2.0	A Glia-to-Neuron Conversion for Treating Oral Cancer Pain	Tao, Feng	Texas A&M University System Health Science Center	$237,500

RP220558	HIHRRA	2.0	Novel Covalent Drugs for BCL6	Fast, Walter	The University of Texas at Austin	$249,999
RP220614	HIHRRA	2.0	Understanding the Impact of Immunity on Premalignant Somatic Mosaicism and Cancer Prevention	Zhu, Hao	The University of Texas Southwestern Medical Center	$237,501
RP220666	HIHRRA	2.0	Targeting Tumors and the Tumor Microenvironment With Banana Lectin-Expressing T Cells	McKenna, Katie	Baylor College of Medicine	$250,000
RP220567	HIHRRA	2.0	Fasting-Induced Microbiome Changes and Radioprotection	Piwnica-Worms, Helen	The University of Texas M. D. Anderson Cancer Center	$249,999
RP220645	HIHRRA	2.0	Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy	Alexandrakis, Georgios	The University of Texas at Arlington	$250,000
RP220581	ECI	2.1	Hyperspectral, Quantitative Intraoperative Fluorescence Image-Guided Brain Surgery	Urban, Randall	The University of Texas Medical Branch at Galveston	$1,494,784
RP220599	CFSA	2.3	Texas Pediatric Cancer Testing (TPCT) Core	Houghton, Peter	The University of Texas Health Science Center at San Antonio	$3,935,480
RP220653	HIHRRA	2.3	Novel Modulators of Genomic Instability in Human Cells	Vasquez, Karen	The University of Texas at Austin	$249,932
RP220587	CFSA	2.3	Advanced Protein Therapeutics Core	Maynard, Jennifer	The University of Texas at Austin	$3,995,180
RP220592	HIHRRA	2.4	Restoration of Phagocytosis Function of Glioma-Associated Microglia/Macrophage by Activating QKI-PPARb-RXRa	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	$250,000
RP220600	HIHRRA	2.4	In Vivo Akt Analysis via Chemical Genetics and Nanoparticle-Mediated Probe Delivery	Wang, Degeng	Texas Tech University	$249,999
RP220610	HIHRRA	2.8	Identification of Enhancers of T-Cell Antitumor Activity in PDAC Using CRISPR Activation Screening	Maitra, Anirban	The University of Texas M. D. Anderson Cancer Center	$250,000

RP220553	HIHRRA	2.9	Reversing Aging-Associated Resistance to Cancer Immunotherapy	Jiang, Wen	The University of Texas M. D. Anderson Cancer Center	$249,976
RP220639	HIHRRA	2.9	Targeting NHE6 to Improve Clinical Efficacy of Daratumumab in Myeloma	Yang, Jing	The Methodist Hospital Research Institute	$250,000

CFSA – Core Facility Support Awards
CTNA - Clinical Trials Network Awards
ECI – Early Clinical Investigator Awards
HIHRA – High-Impact/High Risk Awards

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220030
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 the *Texas Company Product Development Awards* Request for Applications (RFA). CPRIT received 10 applications in response to this RFA. 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

The Product Development Review Council (PDRC) previously reviewed but took no action on this application before recommending it to the PIC on September 1, 2022. This application has a less favorable score than one other application that the PDRC did not recommend within this grant mechanism. The PDRC's final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. 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 after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities 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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/07/2022 12:35 PM CT**

FY:	2022
CYCLE:	2
PROGRAM:	Product Development
MECHANISM:	Texas Company Product Development Research Awards
APPLICATION ID:	DP220030
APPLICATION TITLE	Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of IMSA101 in Combination with Radiotherapy and Checkpoint Inhibitors in Solid Tumor M
APPLICANT NAME:	Sun, Lijun
ORGANIZATION:	ImmuneSensor Therapeutics Inc.
PANEL NAME:	22.2 Product Development Panel-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/25/2022**	06/30/2022
	Method of submission	**CARS**	06/30/2022
	Within receipt period	**YES**	06/30/2022
	Request for extension to submit application after CARS closed	**N/A**	06/30/2022
	Request for extension for late application submission accepted	**N/A**	06/30/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/30/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/30/2022
	Assigned to primary reviewers	**02/17/2022**	06/30/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/11/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/08/2022**	06/30/2022
	Primary Reviewer 3 COI signed	**02/14/2022**	06/30/2022
	Primary Reviewer 4 COI signed	**02/14/2022**	06/30/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/15/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/16/2022**	06/30/2022
	Primary Reviewer 3 critique submitted	**03/17/2022**	06/30/2022
	Primary Reviewer 4 critique submitted	**03/21/2022**	06/30/2022
	COI indicated by non-primary reviewer	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Screening Teleconference Meeting	**03/22/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/23/2022**	06/27/2022
	Post review statements signed	**03/28/2022**	06/27/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/30/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/30/2022
		N/A	06/30/2022

FY:	2022
CYCLE:	2
PROGRAM:	Product Development
MECHANISM:	Texas Company Product Development Research Awards
APPLICATION ID:	DP220030
APPLICATION TITLE	Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of IMSA101 in Combination with Radiotherapy and Checkpoint Inhibitors in Solid Tumor M
APPLICANT NAME:	Sun, Lijun
ORGANIZATION:	ImmuneSensor Therapeutics Inc.
PANEL NAME:	22.2 Product Development Panel-2

Category	Compliance Requirement	Information	Attestation Date
	COI recused from participation		
	Peer Review Meeting	04/13/2022	06/30/2022
	Peer Review Meeting End Date	04/14/2022	06/30/2022
	Post review statements signed	05/10/2022	06/30/2022
	Third Party Observer Report	04/21/2022	06/30/2022
	Score report delivered to CPDO	04/21/2022	06/30/2022
	Recommended for due diligence and IP review	YES	06/30/2022
Due Diligence and IP Review	Final due diligence review submitted to PDRC	06/16/2022	09/06/2022
	Intellectual Property conflict check	04/22/2022	09/06/2022
	Final intellectual property review submitted	06/16/2022	09/06/2022
Final PDRC Recommendation	COI indicated by PDRC member	NONE	07/20/2022
	COI recused from participation	N/A	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	07/14/2022	07/20/2022
	Third Party Observer Report	07/20/2022	07/22/2022
	Recommended for grant award	N/A	07/20/2022
	PDRC Chair Notification to PIC and OC	07/28/2022	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	NONE	07/20/2022
	COI recused from participation (Ranking Meeting)	N/A	07/20/2022
	PDRC Ranking Meeting	07/19/2022	07/20/2022
	Third Party Observer Report	07/20/2022	07/22/2022
	Recommended for grant award	Other: NO ACTION	07/20/2022
	COI indicated by PDRC member (-030 Discussion)	NONE	08/31/2022
	COI recused from participation (-030 Discussion)	N/A	08/31/2022
	Discussion of DP220030 Meeting	08/18/2022	08/31/2022
	Third Party Observer Report	08/22/2022	09/06/2022
	Recommended for grant award	Other: NO ACTION	09/02/2022
	COI indicated by PDRC member (Bi-Weekly Mtg)	NONE	08/31/2022
	COI recused from participation (Bi-Weekly Mtg)	N/A	08/31/2022
	Bi-Weekly PDRC Meeting	08/30/2022	08/31/2022
	Third Party Observer Report	09/02/2022	09/06/2022
	Recommended for grant award	Other: NO ACTION	09/02/2022
	COI indicated by PDRC member (email vote)	None	09/07/2022
	COI recused from participation (email vote)	N/A	09/07/2022
	Email vote	09/01/2022	09/07/2022

CPRIT retains the identity of the attesting party.

FY:	2022
CYCLE:	2
PROGRAM:	Product Development
MECHANISM:	Texas Company Product Development Research Awards
APPLICATION ID:	DP220030
APPLICATION TITLE	Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of IMSA101 in Combination with Radiotherapy and Checkpoint Inhibitors in Solid Tumor M
APPLICANT NAME:	Sun, Lijun
ORGANIZATION:	ImmuneSensor Therapeutics Inc.
PANEL NAME:	22.2 Product Development Panel-2

Category	Compliance Requirement	Information	Attestation Date
	Third party observer report	09/02/2022	09/07/2022
	Recommended for grant award	YES	09/07/2022
	PDRC Chair Notification to PIC and OC	09/01/2022	09/02/2022
PIC Review	COI indicated by PIC member	None	09/07/2022
	COI recused from participation	N/A	09/07/2022
	PIC Review Meeting	09/06/2022	09/07/2022
	Recommended for grant award	YES	09/07/2022
Oversight Committee Approval	CEO Notification to Oversight Committee	N/A	
	COI Indicated by Oversight Committee member	N/A	
	COI Recused from participation	N/A	
	Donation(s) made to CPRIT / foundation	N/A	
	Presented to CPRIT Oversight Committee	N/A	
	Award approved by Oversight Committee	N/A	
	Authority to advance funds requested	N/A	
	Advance authority approved by Oversight Committee	N/A	

Comments:

Comment	Created Date	Created By
No Comment		

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220542
Clinical Trials Network Award

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 *Clinical Trials Network Award* Request for Applications (RFA). CPRIT received two applications in response to this RFA. This application was assigned to the Clinical and Translational Cancer Research panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Clinical Trials Network Award
APPLICATION ID: RP220542
APPLICATION TITLE: Establish the Accelerating Clinical Oncology Research Network - Texas (ACORN-TX) to enhance clinical trial access in North and Central Texas
APPLICANT NAME: Beg, Muhammad S
ORGANIZATION: The University of Texas Southwestern Medical Center
PANEL NAME: 22.2 Clinical and Translational Cancer Research

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/25/2021**	07/19/2022
	RFA Approved by CSO (revised)	**08/31/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/11/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/09/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**03/06/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/27/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/20/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**03/06/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/27/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/20/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/17/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/18/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/20/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/12/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/26/2022**	08/19/2022
	Post review statements signed	**04/29/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220544
Early Clinical Investigator Award

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 *Early Clinical Investigator Award* Request for Applications (RFA). CPRIT received six applications in response to this RFA. This application was assigned to the Clinical and Translational Cancer Research panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Early Clinical Investigator Award
APPLICATION ID: RP220544
APPLICATION TITLE: CPRIT Early Clinical Investigator Award- Christopher Alvarez-Breckenridge
APPLICANT NAME: Draetta, Gulio
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: 22.2 Clinical and Translational Cancer Research

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/10/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/10/2022**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/09/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/21/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**03/06/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/18/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/21/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**03/06/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/14/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/05/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/16/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/20/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/26/2022**	08/19/2022
	Post review statements signed	**04/29/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220553
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Basic Cancer Research 1 panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220553
APPLICATION TITLE: Reversing Aging Associated Resistance to Cancer Immunotherapy
APPLICANT NAME: Jiang, Wen
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: 22.2 Basic Cancer Research-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/04/2022**	08/18/2022
	Method of submission	**CARS**	08/18/2022
	Within receipt period	**YES**	08/18/2022
	Request for extension to submit application after CARS closed	**N/A**	08/18/2022
	Request for extension for late application submission accepted	**N/A**	08/18/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/18/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/18/2022
	Assigned to primary reviewers	**03/07/2022**	08/18/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/18/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/18/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/18/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/18/2022
	COI indicated by non-primary reviewer	**N/A**	08/18/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/18/2022
	Recommended for full review	**N/A**	08/18/2022
	Applicant notified of outcome	**N/A**	08/18/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/18/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 1 critique submitted	**04/12/2022**	08/18/2022
	Primary Reviewer 2 critique submitted	**04/18/2022**	08/18/2022
	Primary Reviewer 3 critique submitted	**03/25/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/16/2022**	08/18/2022
	COI indicated by non-primary reviewer	**Kristin Swanson**	08/18/2022
	COI recused from participation	**YES**	08/18/2022
	Discussed at Peer Review Meeting	**YES**	08/18/2022
	Peer Review Meeting	**04/28/2022**	08/18/2022
	Post review statements signed	**05/10/2022**	08/18/2022
	Third Party Observer Report	**05/03/2022**	08/18/2022
	Score report delivered to CSO	**05/20/2022**	08/18/2022
	Recommended for SRC review	**YES**	08/18/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220558
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Cancer Biology panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220558
APPLICATION TITLE: Novel Covalent Drugs for BCL6
APPLICANT NAME: Fast, Walter
ORGANIZATION: The University of Texas at Austin
PANEL NAME: 22.2 Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**12/20/2021**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/25/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**03/01/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/25/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**03/01/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/26/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/19/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/14/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/08/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/27/2022**	08/19/2022
	Post review statements signed	**06/17/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220567
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Imaging Technology and Informatics panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220567
APPLICATION TITLE: Fasting-induced microbiome changes and radioprotection
APPLICANT NAME: Piwnica-Worms, Helen
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: 22.2 Imaging Technology and Informatics

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**12/22/2021**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/27/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/21/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/24/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/27/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/21/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/24/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/16/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/18/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/22/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/21/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/29/2022**	08/19/2022
	Post review statements signed	**05/04/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220581
Early Clinical Investigator Award

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 *Early Clinical Investigator Award* Request for Applications (RFA). CPRIT received six applications in response to this RFA. This application was assigned to the Clinical and Translational Cancer Research panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Early Clinical Investigator Award
APPLICATION ID: RP220581
APPLICATION TITLE: Hyperspectral, Quantitative Intraoperative Fluorescence Image Guided Brain Surgery
APPLICANT NAME: Urban, Randall J
ORGANIZATION: The University of Texas Medical Branch at Galveston
PANEL NAME: 22.2 Clinical and Translational Cancer Research

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/11/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/10/2022**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/09/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/28/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**03/06/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/28/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**03/06/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/19/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/05/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/18/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/12/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/26/2022**	08/19/2022
	Post review statements signed	**04/29/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220582
Core Facility Support 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 *Core Facility Support Awards* Request for Applications (RFA). CPRIT received 23 applications in response to this RFA. This application was assigned to the Cancer Biology panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Core Facilities Support Awards
APPLICATION ID: RP220582
APPLICATION TITLE: Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UTSouthwestern Medical Center
APPLICANT NAME: Rosen, Michael K
ORGANIZATION: The University of Texas Southwestern Medical Center
PANEL NAME: 22.2 Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/11/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**03/14/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**03/14/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/19/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/15/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**03/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/07/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/27/2022**	08/19/2022
	Post review statements signed	**06/17/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220587
Core Facility Support 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 *Core Facility Support Awards* Request for Applications (RFA). CPRIT received 23 applications in response to this RFA. This application was assigned to the Cancer Biology panel for review and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Core Facilities Support Awards
APPLICATION ID: RP220587
APPLICATION TITLE: Advanced Protein Therapeutics core
APPLICANT NAME: Maynard, Jennifer A
ORGANIZATION: The University of Texas at Austin
PANEL NAME: 22.2 Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/12/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**03/01/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/28/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**03/01/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/28/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/19/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/20/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/19/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/23/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/27/2022**	08/19/2022
	Post review statements signed	**06/17/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220592
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Basic Cancer Research 1 panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220592
APPLICATION TITLE: Restoration of phagocytosis function of glioma-associated microglia/macrophage by activating QKI-PPARb-RXRa
APPLICANT NAME: Hu, Jian
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: 22.2 Basic Cancer Research-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/04/2022**	08/18/2022
	Method of submission	**CARS**	08/18/2022
	Within receipt period	**YES**	08/18/2022
	Request for extension to submit application after CARS closed	**N/A**	08/18/2022
	Request for extension for late application submission accepted	**N/A**	08/18/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/18/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/18/2022
	Assigned to primary reviewers	**03/07/2022**	08/18/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/28/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/19/2022**	08/18/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/18/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/18/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/18/2022
	COI indicated by non-primary reviewer	**N/A**	08/18/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/18/2022
	Recommended for full review	**N/A**	08/18/2022
	Applicant notified of outcome	**N/A**	08/18/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/18/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/28/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/19/2022**	08/18/2022
	Primary Reviewer 1 critique submitted	**04/18/2022**	08/18/2022
	Primary Reviewer 2 critique submitted	**04/20/2022**	08/18/2022
	Primary Reviewer 3 critique submitted	**04/20/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/08/2022**	08/18/2022
	COI indicated by non-primary reviewer	**NONE**	08/18/2022
	COI recused from participation	**N/A**	08/18/2022
	Discussed at Peer Review Meeting	**YES**	08/18/2022
	Peer Review Meeting	**04/28/2022**	08/18/2022
	Post review statements signed	**05/10/2022**	08/18/2022
	Third Party Observer Report	**05/03/2022**	08/18/2022
	Score report delivered to CSO	**05/20/2022**	08/18/2022
	Recommended for SRC review	**YES**	08/18/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220599
Core Facility Support 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 *Core Facility Support Awards* Request for Applications (RFA). CPRIT received 23 applications in response to this RFA. This application was assigned to the Basic Cancer Research 1 panel for review and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Core Facilities Support Awards
APPLICATION ID: RP220599
APPLICATION TITLE: Texas Pediatric Cancer Testing (TPCT) Core
APPLICANT NAME: Houghton, Peter J
ORGANIZATION: The University of Texas Health Science Center at San Antonio
PANEL NAME: 22.2 Basic Cancer Research-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/12/2022**	08/18/2022
	Method of submission	**CARS**	08/18/2022
	Within receipt period	**YES**	08/18/2022
	Request for extension to submit application after CARS closed	**N/A**	08/18/2022
	Request for extension for late application submission accepted	**N/A**	08/18/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/18/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/18/2022
	Assigned to primary reviewers	**03/07/2022**	08/18/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/23/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/28/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/18/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/18/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/18/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/18/2022
	COI indicated by non-primary reviewer	**N/A**	08/18/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/18/2022
	Recommended for full review	**N/A**	08/18/2022
	Applicant notified of outcome	**N/A**	08/18/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/18/2022
	Primary Reviewer 1 COI signed	**02/23/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/28/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 1 critique submitted	**04/20/2022**	08/18/2022
	Primary Reviewer 2 critique submitted	**04/14/2022**	08/18/2022
	Primary Reviewer 3 critique submitted	**04/22/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/16/2022**	08/18/2022
	COI indicated by non-primary reviewer	**Jose Conejo-Garcia**	08/18/2022
	COI recused from participation	**YES**	08/18/2022
	Discussed at Peer Review Meeting	**YES**	08/18/2022
	Peer Review Meeting	**04/28/2022**	08/18/2022
	Post review statements signed	**05/10/2022**	08/18/2022
	Third Party Observer Report	**05/03/2022**	08/18/2022
	Score report delivered to CSO	**05/20/2022**	08/18/2022
	Recommended for SRC review	**YES**	08/18/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220600
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Basic Cancer Research 2 panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220600
APPLICATION TITLE: In vivo Akt Analysis via Chemical Genetics and Nanoparticle-mediated Probe Delivery
APPLICANT NAME: Wang, Degeng
ORGANIZATION: Texas Tech University
PANEL NAME: 22.2 Basic Cancer Research-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/12/2022**	08/18/2022
	Method of submission	**CARS**	08/18/2022
	Within receipt period	**YES**	08/18/2022
	Request for extension to submit application after CARS closed	**N/A**	08/18/2022
	Request for extension for late application submission accepted	**N/A**	08/18/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/18/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/18/2022
	Assigned to primary reviewers	**03/09/2022**	08/18/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/23/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**03/01/2022**	08/18/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/18/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/18/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/18/2022
	COI indicated by non-primary reviewer	**N/A**	08/18/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/18/2022
	Recommended for full review	**N/A**	08/18/2022
	Applicant notified of outcome	**N/A**	08/18/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/18/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/23/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**03/01/2022**	08/18/2022
	Primary Reviewer 1 critique submitted	**04/29/2022**	08/18/2022
	Primary Reviewer 2 critique submitted	**04/26/2022**	08/18/2022
	Primary Reviewer 3 critique submitted	**05/01/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/26/2022**	08/18/2022
	COI indicated by non-primary reviewer	**NONE**	08/18/2022
	COI recused from participation	**N/A**	08/18/2022
	Discussed at Peer Review Meeting	**YES**	08/18/2022
	Peer Review Meeting	**05/05/2022**	08/18/2022
	Post review statements signed	**06/29/2022**	08/18/2022
	Third Party Observer Report	**05/09/2022**	08/18/2022
	Score report delivered to CSO	**05/20/2022**	08/18/2022
	Recommended for SRC review	**YES**	08/18/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220606
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Basic Cancer Research 2 panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:15 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220606
APPLICATION TITLE: Developing a novel optogenetic recombinase system to study and target metastatic cancer
APPLICANT NAME: Maddipati, Ravikanth
ORGANIZATION: The University of Texas Southwestern Medical Center
PANEL NAME: 22.2 Basic Cancer Research-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/11/2022**	08/18/2022
	Method of submission	**CARS**	08/18/2022
	Within receipt period	**YES**	08/18/2022
	Request for extension to submit application after CARS closed	**N/A**	08/18/2022
	Request for extension for late application submission accepted	**N/A**	08/18/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/18/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/18/2022
	Assigned to primary reviewers	**03/09/2022**	08/18/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/28/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**03/03/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/24/2022**	08/18/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/18/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/18/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/18/2022
	COI indicated by non-primary reviewer	**N/A**	08/18/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/18/2022
	Recommended for full review	**N/A**	08/18/2022
	Applicant notified of outcome	**N/A**	08/18/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/18/2022
	Primary Reviewer 1 COI signed	**02/28/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**03/03/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/24/2022**	08/18/2022
	Primary Reviewer 1 critique submitted	**04/26/2022**	08/18/2022
	Primary Reviewer 2 critique submitted	**05/01/2022**	08/18/2022
	Primary Reviewer 3 critique submitted	**04/14/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/23/2022**	08/18/2022
	COI indicated by non-primary reviewer	**NONE**	08/18/2022
	COI recused from participation	**N/A**	08/18/2022
	Discussed at Peer Review Meeting	**YES**	08/18/2022
	Peer Review Meeting	**05/05/2022**	08/18/2022
	Post review statements signed	**06/29/2022**	08/18/2022
	Third Party Observer Report	**05/09/2022**	08/18/2022
	Score report delivered to CSO	**05/20/2022**	08/18/2022
	Recommended for SRC review	**YES**	08/18/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application RP220610
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Basic Cancer Research 1 panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220610
APPLICATION TITLE: Identification of enhancers of T-cell anti-tumor activity in PDAC using CRISPR activation screening
APPLICANT NAME: Maitra, Anirban
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: 22.2 Basic Cancer Research-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/05/2022**	08/18/2022
	Method of submission	**CARS**	08/18/2022
	Within receipt period	**YES**	08/18/2022
	Request for extension to submit application after CARS closed	**N/A**	08/18/2022
	Request for extension for late application submission accepted	**N/A**	08/18/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/18/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/18/2022
	Assigned to primary reviewers	**03/07/2022**	08/18/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/21/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/23/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/19/2022**	08/18/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/18/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/18/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/18/2022
	COI indicated by non-primary reviewer	**N/A**	08/18/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/18/2022
	Recommended for full review	**N/A**	08/18/2022
	Applicant notified of outcome	**N/A**	08/18/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/18/2022
	Primary Reviewer 1 COI signed	**02/21/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/23/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/19/2022**	08/18/2022
	Primary Reviewer 1 critique submitted	**04/21/2022**	08/18/2022
	Primary Reviewer 2 critique submitted	**04/23/2022**	08/18/2022
	Primary Reviewer 3 critique submitted	**04/20/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/14/2022**	08/18/2022
	COI indicated by non-primary reviewer	**NONE**	08/18/2022
	COI recused from participation	**N/A**	08/18/2022
	Discussed at Peer Review Meeting	**YES**	08/18/2022
	Peer Review Meeting	**04/28/2022**	08/18/2022
	Post review statements signed	**05/10/2022**	08/18/2022
	Third Party Observer Report	**05/03/2022**	08/18/2022
	Score report delivered to CSO	**05/20/2022**	08/18/2022
	Recommended for SRC review	**YES**	08/18/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220614
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Cancer Biology panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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

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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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220614
APPLICATION TITLE: Understanding the impact of immunity on pre-malignant somatic mosaicism and cancer prevention
APPLICANT NAME: Zhu, Hao
ORGANIZATION: The University of Texas Southwestern Medical Center
PANEL NAME: 22.2 Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
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	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/24/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/24/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/21/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/13/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/16/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/23/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/27/2022**	08/19/2022
	Post review statements signed	**06/17/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220626
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Basic Cancer Research 1 panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220626
APPLICATION TITLE: A glia-to-neuron conversion for treating oral cancer pain
APPLICANT NAME: Tao, Feng
ORGANIZATION: Texas A&M University System Health Science Center
PANEL NAME: 22.2 Basic Cancer Research-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/12/2022**	08/18/2022
	Method of submission	**CARS**	08/18/2022
	Within receipt period	**YES**	08/18/2022
	Request for extension to submit application after CARS closed	**N/A**	08/18/2022
	Request for extension for late application submission accepted	**N/A**	08/18/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/18/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/18/2022
	Assigned to primary reviewers	**03/07/2022**	08/18/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/18/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/18/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/18/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/18/2022
	COI indicated by non-primary reviewer	**N/A**	08/18/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/18/2022
	Recommended for full review	**N/A**	08/18/2022
	Applicant notified of outcome	**N/A**	08/18/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/18/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/18/2022
	Primary Reviewer 1 critique submitted	**03/28/2022**	08/18/2022
	Primary Reviewer 2 critique submitted	**04/16/2022**	08/18/2022
	Primary Reviewer 3 critique submitted	**04/21/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/16/2022**	08/18/2022
	COI indicated by non-primary reviewer	**NONE**	08/18/2022
	COI recused from participation	**N/A**	08/18/2022
	Discussed at Peer Review Meeting	**YES**	08/18/2022
	Peer Review Meeting	**04/28/2022**	08/18/2022
	Post review statements signed	**05/10/2022**	08/18/2022
	Third Party Observer Report	**05/03/2022**	08/18/2022
	Score report delivered to CSO	**05/20/2022**	08/18/2022
	Recommended for SRC review	**YES**	08/18/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220631
Core Facility Support 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 *Core Facility Support Awards* Request for Applications (RFA). CPRIT received 23 applications in response to this RFA. This application was assigned to the Clinical and Translational Cancer Research panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Core Facilities Support Awards
APPLICATION ID: RP220631
APPLICATION TITLE: West Texas Pharmacology Core
APPLICANT NAME: Kang, Min H
ORGANIZATION: Texas Tech University Health Sciences Center
PANEL NAME: 22.2 Clinical and Translational Cancer Research

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/10/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/09/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/20/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/26/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/25/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/19/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/20/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/26/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/25/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/19/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/18/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/18/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/18/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/17/2022**	08/19/2022
	COI indicated by non-primary reviewer	**W. Martin Kast**	08/19/2022
	COI recused from participation	**YES**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/26/2022**	08/19/2022
	Post review statements signed	**04/29/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220639
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Clinical and Translational Cancer Research panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220639
APPLICATION TITLE: Targeting NHE6 to improve clinical efficacy of daratumumab in myeloma
APPLICANT NAME: Yang, Jing
ORGANIZATION: The Methodist Hospital Research Institute
PANEL NAME: 22.2 Clinical and Translational Cancer Research

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/04/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/09/2022**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/09/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/23/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/20/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/18/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/19/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/23/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/20/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/18/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/19/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/17/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/18/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/22/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/31/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/26/2022**	08/19/2022
	Post review statements signed	**04/29/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220645
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Imaging Technology and Informatics panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220645
APPLICATION TITLE: Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy
APPLICANT NAME: Alexandrakis, Georgios
ORGANIZATION: The University of Texas at Arlington
PANEL NAME: 22.2 Imaging Technology and Informatics

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/10/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/20/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/20/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/25/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/16/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/19/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/15/2022**	08/19/2022
	COI indicated by non-primary reviewer	**Arion-Xenofon Chatziioannou**	08/19/2022
	COI recused from participation	**YES**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/29/2022**	08/19/2022
	Post review statements signed	**05/04/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220646
Core Facility Support 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 *Core Facility Support Awards* Request for Applications (RFA). CPRIT received 23 applications in response to this RFA. This application was assigned to the Cancer Biology panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Core Facilities Support Awards
APPLICATION ID: RP220646
APPLICATION TITLE: Patient-derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas
APPLICANT NAME: Lewis, Michael T
ORGANIZATION: Baylor College of Medicine
PANEL NAME: 22.2 Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/11/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/25/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/18/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/25/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/18/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**07/27/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/19/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/13/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/23/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/27/2022**	08/19/2022
	Post review statements signed	**06/17/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

Comments:

Comment	Created Date	Created By
Primary Reviewer 1 critique submitted date reflects date uploaded to P2RMIS by Scientific Review Manager; critique was previously submitted directly from reviewer to SRM on 5/17/22.	**2022-08-01 12:27:49.773**	**Chumbris, Aaron**

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220650
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Cancer Biology panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220650
APPLICATION TITLE: Targeting Nitric Oxide Synthase (NOS) pathway to remodel obesity induced tumor inflammation in patients with TNBC
APPLICANT NAME: Chang, Jenny C
ORGANIZATION: The Methodist Hospital Research Institute
PANEL NAME: 22.2 Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/11/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**03/01/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/28/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**03/01/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/28/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/07/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/20/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/19/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/08/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/27/2022**	08/19/2022
	Post review statements signed	**06/17/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220653
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Basic Cancer Research 2 panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022..

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220653
APPLICATION TITLE: Novel Modulators of Genomic Instability in Human Cells
APPLICANT NAME: Vasquez, Karen M
ORGANIZATION: The University of Texas at Austin
PANEL NAME: 22.2 Basic Cancer Research-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/12/2022**	08/18/2022
	Method of submission	**CARS**	08/18/2022
	Within receipt period	**YES**	08/18/2022
	Request for extension to submit application after CARS closed	**N/A**	08/18/2022
	Request for extension for late application submission accepted	**N/A**	08/18/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/18/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/18/2022
	Assigned to primary reviewers	**03/09/2022**	08/18/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/28/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/23/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**03/02/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**03/01/2022**	08/18/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/18/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/18/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/18/2022
	COI indicated by non-primary reviewer	**N/A**	08/18/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/18/2022
	Recommended for full review	**N/A**	08/18/2022
	Applicant notified of outcome	**N/A**	08/18/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/18/2022
	Primary Reviewer 1 COI signed	**02/28/2022**	08/18/2022
	Primary Reviewer 2 COI signed	**02/23/2022**	08/18/2022
	Primary Reviewer 3 COI signed	**03/02/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 COI signed	**03/01/2022**	08/18/2022
	Primary Reviewer 1 critique submitted	**04/20/2022**	08/18/2022
	Primary Reviewer 2 critique submitted	**04/26/2022**	08/18/2022
	Primary Reviewer 3 critique submitted	**04/24/2022**	08/18/2022
	Primary (Advocate) Reviewer 4 critique submitted	**04/26/2022**	08/18/2022
	COI indicated by non-primary reviewer	**NONE**	08/18/2022
	COI recused from participation	**N/A**	08/18/2022
	Discussed at Peer Review Meeting	**YES**	08/18/2022
	Peer Review Meeting	**05/05/2022**	08/18/2022
	Post review statements signed	**06/29/2022**	08/18/2022
	Third Party Observer Report	**05/09/2022**	08/18/2022
	Score report delivered to CSO	**05/20/2022**	08/18/2022
	Recommended for SRC review	**YES**	08/18/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220662
Core Facility Support 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 *Core Facility Support Awards* Request for Applications (RFA). CPRIT received 23 applications in response to this RFA. This application was assigned to the Cancer Biology panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: Core Facilities Support Awards
APPLICATION ID: RP220662
APPLICATION TITLE: UTHSCSA Cancer Genome Sequencing and Computation Core
APPLICANT NAME: Chen, Yidong
ORGANIZATION: The University of Texas Health Science Center at San Antonio
PANEL NAME: 22.2 Cancer Biology

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/12/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/07/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/07/2022**	08/19/2022
	Primary Reviewer 1 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/17/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/17/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/19/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**03/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/08/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/27/2022**	08/19/2022
	Post review statements signed	**06/17/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP220666
High-Impact/High-Risk 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 89 applications in response to this RFA. This application was assigned to the Clinical and Translational Cancer Research panel and, along with other cycle 22.2 applications, reviewed during meetings held on April 26 through May 5, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle. The Scientific Review Council (SRC) made a final recommendation to the PIC regarding this application on September 1, 2022.

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 member has an approved conflict of interest waiver on file for FY2023: 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).

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 7 day of September, 2022, 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: 09/06/2022 06:16 PM CT

FY: 2022
CYCLE: 2
PROGRAM: Research
MECHANISM: High-Impact/High-Risk Research Awards
APPLICATION ID: RP220666
APPLICATION TITLE: Targeting Tumors and the Tumor Microenvironment with Banana Lectin Expressing T cells
APPLICANT NAME: McKenna, Katie
ORGANIZATION: Baylor College of Medicine
PANEL NAME: 22.2 Clinical and Translational Cancer Research

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**08/18/2021**	07/19/2022
	RFA published in Texas.gov eGrants	**09/01/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) opened	**10/13/2021**	07/19/2022
	CPRIT Application Receipt System (CARS) closed	**01/12/2022**	07/19/2022
	Date application submitted	**01/11/2022**	08/19/2022
	Method of submission	**CARS**	08/19/2022
	Within receipt period	**YES**	08/19/2022
	Request for extension to submit application after CARS closed	**N/A**	08/19/2022
	Request for extension for late application submission accepted	**N/A**	08/19/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	08/19/2022
	Donation(s) made to CPRIT / foundation	**NO**	08/19/2022
	Assigned to primary reviewers	**03/09/2022**	08/19/2022
	Applicant notified of review panel assignment	**02/11/2022**	07/19/2022
	Primary Reviewer 1 COI signed	**02/21/2022**	08/19/2022
	Primary Reviewer 2 COI signed	**02/22/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/18/2022**	08/19/2022
Preliminary Evaluation	**Primary Reviewer 1 critique submitted**	**N/A**	08/19/2022
	Primary Reviewer 2 critique submitted	**N/A**	08/19/2022
	Primary Reviewer 3 critique submitted	**N/A**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**N/A**	08/19/2022
	COI indicated by non-primary reviewer	**N/A**	08/19/2022
	Preliminary Evaluation score summary sent to Chair	**N/A**	08/19/2022
	Recommended for full review	**N/A**	08/19/2022
	Applicant notified of outcome	**N/A**	08/19/2022
Peer Review Meeting	**Assigned to primary reviewers**	**03/09/2022**	08/19/2022
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	Primary Reviewer 2 COI signed	**02/22/2022**	08/19/2022
	Primary Reviewer 3 COI signed	**02/17/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 COI signed	**02/18/2022**	08/19/2022
	Primary Reviewer 1 critique submitted	**04/20/2022**	08/19/2022
	Primary Reviewer 2 critique submitted	**04/06/2022**	08/19/2022
	Primary Reviewer 3 critique submitted	**04/13/2022**	08/19/2022
	Primary (Advocate) Reviewer 4 critique submitted	**03/20/2022**	08/19/2022
	COI indicated by non-primary reviewer	**NONE**	08/19/2022
	COI recused from participation	**N/A**	08/19/2022
	Discussed at Peer Review Meeting	**YES**	08/19/2022
	Peer Review Meeting	**04/26/2022**	08/19/2022
	Post review statements signed	**04/29/2022**	08/19/2022
	Third Party Observer Report	**05/03/2022**	08/19/2022
	Score report delivered to CSO	**05/20/2022**	08/19/2022
	Recommended for SRC review	**YES**	08/19/2022
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	09/01/2022
	COI recused from participation	**N/A**	09/01/2022
	SRC Meeting	**09/01/2022**	09/01/2022
	Third Party Observer Report	**09/02/2022**	09/06/2022
	Recommended for grant award	**YES**	09/01/2022
	SRC Chair Notification to PIC and OC	**09/01/2022**	09/06/2022
PIC Review	**COI indicated by PIC member**	**None**	09/06/2022
	COI recused from participation	**N/A**	09/06/2022
	PIC Review Meeting	**09/06/2022**	09/06/2022
	Recommended for grant award	**YES**	09/06/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.