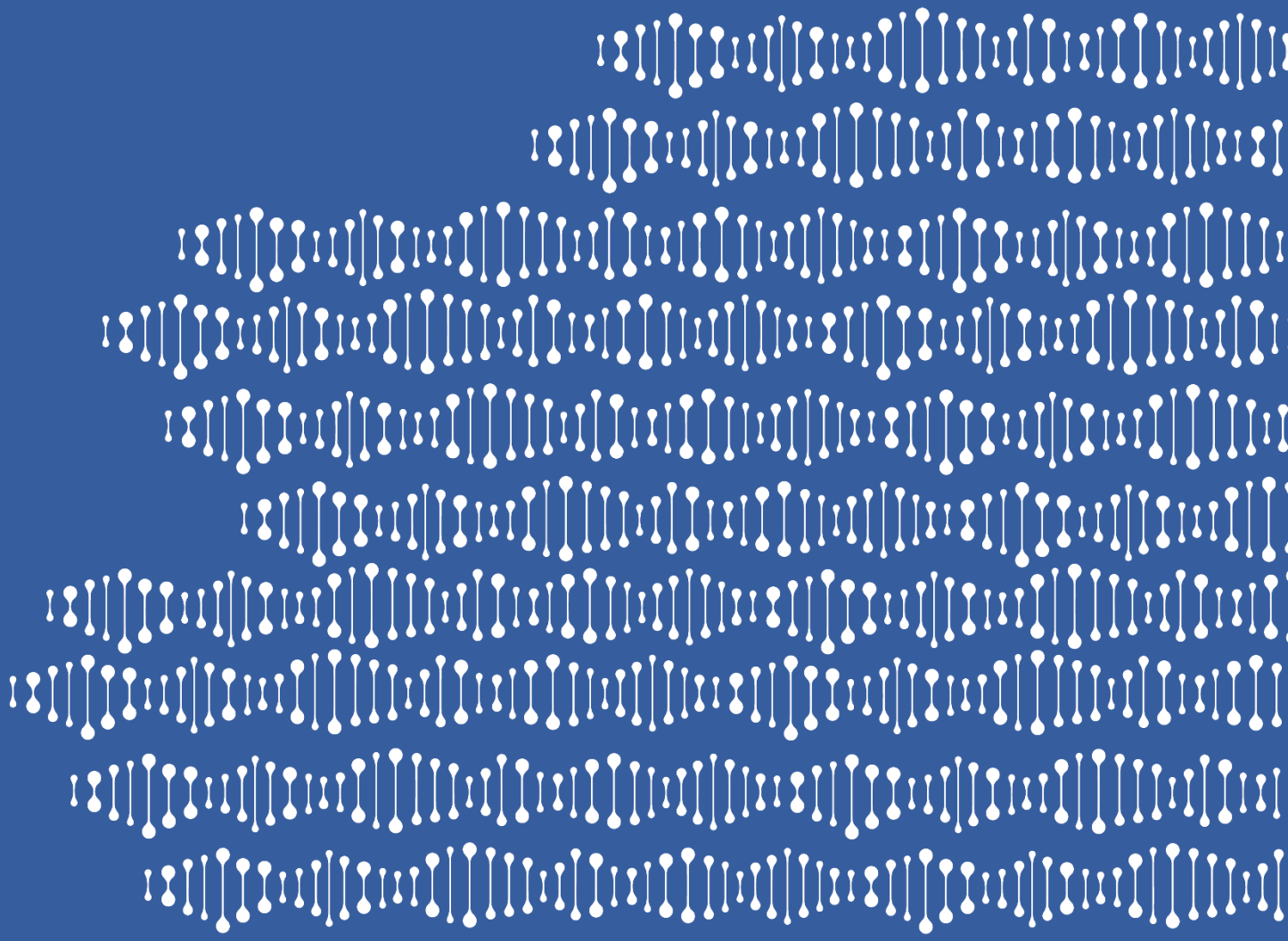
Cancer Prevention & Research Institute of Texas

Proposed Grant Awards

November 20, 2024



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE

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

SUBJECT: RECRUITMENT AWARD RECOMMENDATIONS FY2025, CYCLE 25.1

DATE: NOVEMBER 20, 2024

The Scientific Review Council (SRC) reviewed 20 CPRIT Scholar Nominations for FY2025 Recruitment Cycle 25.1, including one Recruitment of an Established Investigator award, five Recruitment of Rising Stars awards, and 14 Recruitment of First-Time, Tenure-Track Faculty Member awards. SRC recommendations for FY2025 Recruitment Cycle 25.1 include **five awards** from two grant mechanisms totaling **$12,000,000** as displayed in Table 1.

Table 1.

Grant Mechanism	**SRC Recommendations**	
	Awards	**Funding**
Recruitment of Rising Stars	1	$4,000,000
Recruitment of First-Time, Tenure-Track Faculty Members	4	$8,000,000
Total	**5**	**$12,000,000**

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

Table 2.

Program Priorities Addressed by Grant Recommendations		
# Awards*	**Program Priorities**	**Funding***
5	Recruitment of outstanding cancer researchers to Texas	$12,000,000
5	A broad range of innovative, investigator-initiated research projects	$12,000,000
1	Drug discovery	$2,000,000
1	Computational oncology and analytical methods	$2,000,000
*Some grant awards address more than one program priority and are double counted.		

1. RECRUITMENT OF RISING STARS (FY25.1, Cycle 25.1) Slate

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

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

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

Recommended Awards:
Five Recruitment of Rising Stars grant applications were submitted and one was recommended by the Scientific Review Council for an award.

Below is a listing of the candidate with their associated expertise:

RR250048
Candidate: Daniel Addison, M.D
Funding Mechanism: Recruitment of Rising Stars
Applicant Organization: University of Texas Southwestern Medical Center
Original Organization of Nominee: The Ohio State University
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]:1.1
Recommended Total Budget Award and Duration: $4,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, A broad range of innovative, investigator-initiated research projects

Description:
Daniel Addison, M.D. is being recruited to The University of Texas Southwestern Medical Center's Division of Cardiovascular Medicine in the Department of Internal Medicine as an Associate Professor with a secondary appointment in the Simmons Comprehensive Cancer Center. Dr. Addison – who has been nominated for a CPRIT Rising Star Scholar Award - has received international recognition for his seminal work in the emerging field of cardio-oncology,

which has informed our understanding of cardiovascular effects of targeted and immune-based cancer therapeutics, particularly in patients with hematologic malignancies. Dr. Addison's early work was focused on cardiotoxicity related to Bruton tyrosine kinase inhibitors (BTKI). Specifically, he has developed the first prospective deep phenotyping study to uncover mechanisms by which these agents contribute to atrial fibrillation - an important complication of various cancer therapies. As evidence of his stature in the field, Dr. Addison has served in leadership roles at the American Heart Association (AHA) and American College of Cardiology, including serving as Vice Chair (and now Chair) of the AHA Cardiac Imaging Committee, and serving on the leadership counsel of both the American College of Cardiology's and AHA's cardio-oncology counsels.

Leveraging leading-edge multimodal cardiovascular imaging and translational approaches, Dr. Addison leads a dynamic cardio-oncology and imaging research program. Using unique animal and human models, he previously showed that early and later forms of heart toxicity caused by cancer treatments are the result of exaggerated responses of the body's natural defense systems, and may be mediated by mutations in genes within blood cells that develop over time and can lead to inflammation, called clonal hematopoiesis (CH). At UT Southwestern, he will continue to build on this platform as a logical continuation of his ongoing NCI/NIH-funded studies, and will test the hypothesis that CH leads to increased risk of heart toxicity, and that blocking molecular pathways triggered by CH with a targeted medication will prevent and reduce the severity of this debilitating side effect without affecting anticancer efficacy.

In Aim 1, he will continue the analysis of BTKI cardiotoxicity and explore how targeted immune inhibition affects cardiotoxic risk. In Aim 2, he proposes an investigator-initiated clinical trial evaluating the role of targeted inflammatory pathway inhibition for cardiotoxicity prevention among patients with hematological cancers, and will explore the effect of CH on treatment efficacy as part of a new UT Southwestern-led cardio-oncology clinical trials consortium. In Aim 3, he will expand immune profiling studies by establishing a combined imaging and genomics (radio-genomics) biorepository to define the role of pro-inflammatory clinical and molecular alterations in cardiotoxicity and other adverse events in cancer patients during and after cancer treatment. Successful completion of these studies will lead to the identification of pathways that can be targeted for cardiotoxicity prevention, and will inform new immune-based paradigms to prevent cardio-vascular disease in cancer patients.

2. RECRUITMENT OF FIRST-TIME TENURE-TRACK FACULTY MEMBERS (RFA R-25.1 – Cycle 25.1) Slate

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:
Fourteen Recruitment of First-Time, Tenure-Track Faculty Member grant applications were submitted and four were recommended by the Scientific Review Council for an award.

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

RR250017
Candidate: Fangyu Liu, Ph.D.
Funding Mechanism: Recruitment of First-Time, Tenure-Track Faculty Member
Applicant Organization: The University of Texas Southwestern Medical Center
Original Organization of Nominee: University of California, San Francisco
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]:1.0
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, A broad range of innovative, investigator-initiated research projects, Drug, Discovery, Computational oncology and analytic methods.

Description:
The University of Texas Southwestern Medical Center has nominated Fangyu Liu, Ph.D. for a CPRIT First-Time, Tenure-Track Faculty Member Award, and appointment as an Assistant Professor in the Department of Pharmacology and the Simmons Comprehensive Cancer Center. Dr. Liu has an interdisciplinary background in structural biology and computer-aided structure-based drug discovery. During her graduate and postdoctoral training, Dr. Liu elucidated unique structural features underlying the function of the human transmembrane receptor altered in cystic fibrosis (CFTR) and the mechanisms by which cystic fibrosis drugs modulate its function. Utilizing structure-based virtual screening, she has also identified novel drug candidates for parathyroid disorders, one of which has demonstrated increased in vivo potency and reduced side effects. She has five publications in the highest-profile journals, and is the recipient of the prestigious Damon Runyon Postdoctoral Fellowship Award.

As a faculty member at UT Southwestern, Dr. Liu will focus on the precise targeting of membrane enzymes to understand cancer biology and impact cancer progression in pancreatic ductal adenocarcinoma. Specifically, Dr. Liu proposes to exploit structure-based drug design methodology initially to develop drugs that target two key pathways that promote cancer. First, she will develop inhibitors of Wnt signaling – a pathway that promotes cell growth. Second, she will develop inhibitors of proteins that suppress ferroptosis (a type of cell death dependent on iron), enabling cell death to occur in response to cancer therapies. A particularly innovative

basis for her project stems from her discovery that her method can be used to identify novel chemical probes that selectively retain desirable clinical effects while eliminating on-target toxic side effects. Such compounds would be game changers for targeting difficult to treat cancers.

RR250052
Candidate: Xiangdong Lv, Ph.D.
Funding Mechanism: Recruitment of First-Time, Tenure-Track Faculty Member
Applicant Organization: University of Texas Health Science Center at Houston
Original Organization of Nominee: Baylor College of Medicine
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]:1.0
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, A broad range of innovative, investigator-initiated research projects.

Description:
Xiangdong Lv, Ph.D. has been nominated by the University of Texas Health Science Center at Houston for a CPRIT Recruitment Award as a First-Time, Tenure-Track Faculty Member. He is being recruited to the Center for Translational Cancer Research, Brown Foundation Institute of Molecular Medicine at McGovern Medical School. During his postdoctoral training at Baylor College of Medicine with Dr. Xi Chen, a CPRIT Scholar, he made a fundamental discovery that revealed how tumor cells undergo reprogramming of proteostasis - the dynamic regulation of a balanced and functional set of proteins within a cell or tissue – by increasing protein synthesis to develop resistance to KRAS inhibitors. KRAS is one of the most frequently mutated genes in human cancer, and controls a critical cell signaling pathway. Dr. Lv also found that KRAS drug-resistant cancer cells are highly vulnerable to the blockade of protein synthesis, suggesting a potential new approach to overcome resistance to KRAS-targeting drugs. The work - published in *Science* - was widely recognized as a potential breakthrough discovery in understanding resistance to KRAS inhibitors.

These important findings formed the basis of the new studies proposed for his independent laboratory to uncover additional mechanisms of drug resistance to KRAS inhibitors and to identify new approaches and drug candidates to overcome drug resistance to this new class of cancer therapeutics. Specifically, he proposes (Aim 1) to determine the dynamic alterations of protein synthesis in response to KRAS signaling inhibition; (Aim 2) to delineate the molecular mechanism underlying protein synthesis reprogramming in response to KRAS inhibition; and (Aim 3) to target heightened protein synthesis to overcome therapy resistance to KRAS inhibitors. Ultimately, this research will identify actionable vulnerabilities of therapy-resistant tumors and provide new avenues to prevent recurrence.

RR250002
Candidate: Norihiro Goto, M.D., Ph.D.
Funding Mechanism: Recruitment of First-Time, Tenure-Track Faculty Member
Applicant Organization: University of Texas MD Anderson Cancer Center
Original Organization of Nominee: Massachusetts Institute of Technology
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]:1.1

Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, A broad range of innovative, investigator-initiated research projects.

Description:
The University of Texas MD Anderson Cancer Center is nominating Norihiro Goto, M.D., Ph.D., for a First-Time, Tenure-Track CPRIT Scholar Award. Dr. Goto - an outstanding physician-scientist with substantial expertise in intestinal stem cell and cancer biology - is being recruited as an Assistant Professor in the Department of Gastroenterology, Hepatology and Nutrition. During his post-doctoral training, Dr. Goto elucidated the mechanism by which early colon cancers initiate an immune evasion program, research that was recently published in *Nature*. He also developed novel tools to investigate the role of the surrounding niche cells that support intestinal stem cells.

Building on these discoveries and newly developed tools, Dr. Goto plans to elucidate how niche cells contribute to immune evasion and distant metastasis in colon cancer, and to develop novel therapeutic approaches by targeting niche cells. Dr. Goto's research program has the potential to dramatically improve the prognosis of colon cancer patients by addressing two major challenges in the treatment of colon cancer: immune evasion and liver metastasis. To this end, he has established novel organoid co-culture systems and genetically engineered mouse models to investigate the interaction between tumor cells and their niche cells. Additionally, he has established pro-metastatic colon cancer organoid lines and a state-of-the-art orthotopic transplantation mouse model to recapitulate the tumor progression from primary tumors to liver metastases. Specific Aim 1 will decipher how niche cells contribute to immune evasion of colon cancer. Specific Aim 2 will decipher how niche cells contribute to liver metastasis. The therapeutic approaches to enhance tumor immunity and prevent liver metastasis through targeting niche cells would represent a breakthrough in cancer therapy, and have the potential to dramatically improve the prognosis for patients with colon cancer.

RR250014
Candidate: Xufeng Chen, Ph.D.
Funding Mechanism: Recruitment of First-Time, Tenure-Track Faculty Member
Applicant Organization: University of Texas MD Anderson Cancer Center
Original Organization of Nominee: New York University
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]:1.1
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas, A broad range of innovative, investigator-initiated research projects.

Description:
The University of Texas MD Anderson Cancer Center seeks to recruit Xufeng Chen, Ph.D., as a First-Time, Tenure-Track CPRIT Scholar and Assistant Professor in the Department of Hematopoietic Biology and Malignancy. Dr. Chen is an exceptionally talented fundamental cancer immunologist studying hematological cancers with an emphasis on drug resistance.

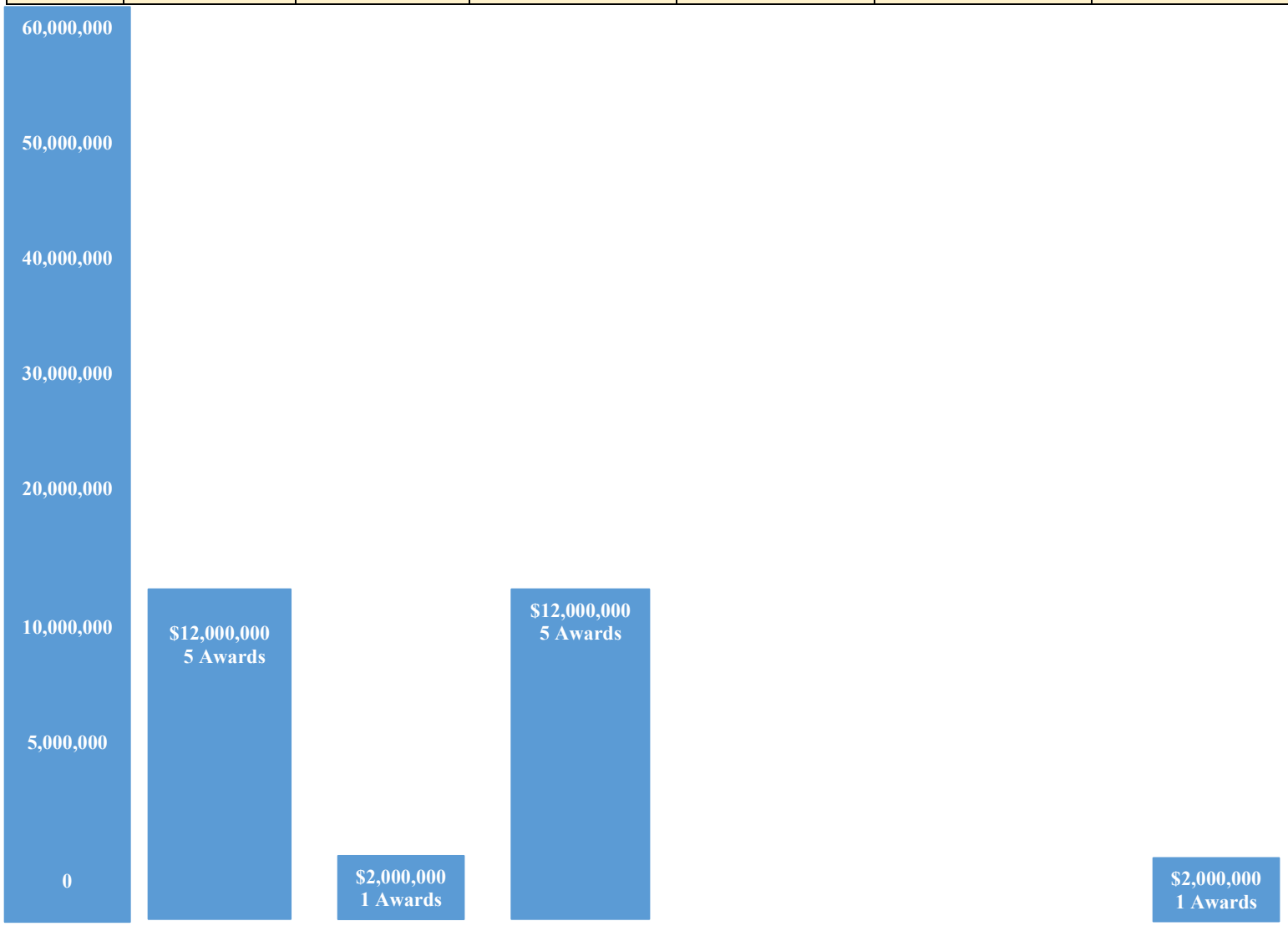
Immunotherapy has revolutionized cancer treatment, but its application in Acute Myeloid Leukemia (AML), an aggressive hematopoietic neoplasm, has been largely disappointing. One potential reason is that AML cells can evade immune surveillance by suppressing their own ability to evoke an immune response, and by actively suppressing the function of the immune system by creating an "immunosuppressive environment", which dampens the efficacy of immunotherapy. The overall goal of Dr. Chen's proposal is to understand the mechanisms by which AML dysregulates these processes, how this affects immunotherapy, and how we can effectively reverse immune evasion to improve outcomes.

To achieve these goals, he has developed a target discovery platform and found several key factors that help AML cells prevent immune recognition and killing. Initially, he will test the concept of blocking these factors to make AML cells more detectable and vulnerable to the immune system, potentially improving immunotherapy. He will then use advanced single-cell approaches to determine the spatiotemporal signatures in both AML and immune cells that could be used to predict immunotherapy outcomes. Finally, he will profile the AML-interacting immune cells within the "immunosuppressive environment" and use comprehensive functional screenings to identify key components that mediate the direct interactions between AML and immune cells over time.

The completion of this innovative proposal will provide critical mechanistic insights for clarifying the immune evasion processes in AML patients, which could identify biomarkers that predict successful immunotherapy outcomes. From a therapeutic perspective, this proposal will develop novel approaches for discovering therapeutic targets, as well as "toolkits" for identifying and evaluating druggable targets for restoring the immune system's ability to reject leukemia cells. Importantly, these powerful "toolkits" can be extended beyond AML to other cancers.

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	Drug Discovery	A broad range of innovative, investigator-initiated research projects.	Childhood and Adolescent Cancers	Population Disparities	Computational oncology and analytic methods	Hepatocellular Cancer



- **Recruitment of Rising Stars (RFA R-25-1 RRS):**
  Recruits outstanding mid-level investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.
  Award: Up to $4 million over a period of five years.

- **Recruitment of First-Time, Tenure-Track Faculty Members (RFA R-25-1. RFT**):
  Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research.
  Award: Up to $2 million over a period of up to five years.

UC San Diego
SCHOOL OF MEDICINE

October 16, 2024

Dr. David A. Cummings, M.D.
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dcummingsmd@yahoo.com

Ms. Kristen Doyle
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to kdoyle@cprit.texas.gov

Dear Dr. Cummings and Ms. Doyle,

The Scientific Review Council (SRC) is pleased to submit this list of five Recruitment grant recommendations for the Recruitment of Rising Stars and Recruitment of First-Time, Tenure-Track Faculty Members.

The SRC met on September 12, 2024, to review Recruitment of Established Investigators, Rising Start and First-Time Tenure-Track Faculty Members applications submitted for Cycle FY2025.1

Recommended funding amounts and the overall evaluation score are stated for each grant application in the following table. The total amount for the applications recommended to the PIC is $12,000,000.

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

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Rank	ID	RFA	Application Title	PI	PI Org.	Rec. Budget	Score
1	RR250017	RFTFM	Targeting Membrane Enzymes by Structure-Based Drug Discovery for Pancreatic Ductal Adenocarcinoma	Fangyu Liu, Ph.D.	The University of Texas Southwestern Medical Center	$ 2,000,000.00	**1.0**
2	RR250052	RFTFM	Harnessing Protein Translation Machinery to Overcome Resistance of KRAS Inhibitors	Xiangdong Lv, Ph. D	The University of Texas Health Science Center at Houston	$ 2,000,000.00	**1.0**
3	RR250002	RFTFM	Dissecting Niche Cells in Cancer Immunity and Metastasis	Norihiro Goto, M.D., Ph.D.	The University of Texas M. D. Anderson Cancer Center	$ 2,000,000.00	**1.1**
4	RR250014	RFTFM	Decoding the Immune Network Dynamics in Acute Myeloid Leukemia	Xufeng Chen, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$ 2,000,000.00	**1.1**
5	RR250048	RRS	Novel clinical biomarkers and mechanisms of Cardiotoxicity	Daniel Addison, M.D.	The University of Texas Southwestern Medical Center	$ 4,000,000.00	**1.1**

Recruitment of Rising Stars
Recruitment of First-Time, Tenure Track Faculty Members (RFTTFM)

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER
SUBJECT: PREVENTION GRANT RECOMMENDATIONS – FY 2025 CYCLE 1
DATE: NOVEMBER 7, 2024

Summary and Recommendation:
The Program Integration Committee (PIC) has completed its review of the recommendations forwarded by the Prevention Review Council (PRC) and recommends awarding 8 projects for FY 2025 Cycle 1 totaling $13,446,501. The grant recommendations are presented in three slates.

Grant Mechanism	Number	Amount
Cancer Screening and Early Detection	6	$11,996,572
Primary Prevention of Cancer	1	$ 1,000,000
Dissemination of CPRIT-Funded Cancer Control Interventions	1	$ 449,929

Background:

FY 2025 Cycle 1 (25.1)
The Prevention Program released three RFAs, *Primary Prevention of Cancer, Cancer Screening and Early Detection*, and *Dissemination of CPRIT-Funded Cancer Control Interventions* on February 9, 2024, for the first cycle of FY 2025. CPRIT received 24 proposals totaling $33,843,921 by the June 6 deadline. Four applications were administratively withdrawn as they were not responsive to the RFAs. Peer review took place on September 10 and 11, 2024, and the Prevention Review Council (PRC) met on October 18, 2024, to make recommendations to the Program Integration Committee (PIC). Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in November.

Program Priorities Addressed
All the recommended applications address more than one of the Prevention Program priorities. See the attached chart for additional detail.

Number of Applications Addressing Priorities		Amount
8	Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence	$13,446,501
8	Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence	$13,446,501
8	Prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services	$13,446,501

Prevention Program Slates

Cancer Screening and Early Detection

Mechanism:
This award mechanism seeks to support the delivery of evidence-based clinical services to screen for cancer and pre-cancer in underserved populations who do not have adequate access to cancer early detection interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community, have nationally recommended screening methods, and use evidence-based methods to screen for these cancers.

Award: Maximum of $1M for new projects and $2.5M for expansion projects; maximum duration of 5 years

Recommended projects (6): $11,996,572

Fourteen applications were submitted in this mechanism. Six *Cancer Screening and Early Detection* projects are recommended.

Project Descriptions

PP250006	Expansion of Cancer Screening and Early Detection Services to Rural & Medically Underserved Communities	Duckworth, Jessica	The Rose	2.7	$2,500,000
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services					

The Empower Her® to Care Project 7 (EHC7) proposes to deliver breast cancer screening, diagnostic procedures, and patient navigation services to under resourced residents in a 45-county services area. This service area has a population of over 2 million uninsured residents and 1.4 million residents living in poverty. EHC7 employs multicomponent, evidence-based strategies and interventions and focuses on three strategic categories – increasing community

demand, increasing community access, and increasing provider delivery. Community Engagement Navigators (CENs) will be assigned to engage the community and clinical partners

to schedule outreach and education activities and mobile mammography events. The CENs will also navigate patients into screening and diagnostic care and follow the patient to resolve their clinical process. The EHC7 also removes the financial barrier to screening and breast care and ensures women comply with recommended screening or follow-up care. Uninsured women who meet program eligibility guidelines will have no out-of-pocket cost. EHC7 will utilize the mobile mammography program to remove transportation and access issues for women in the service area.

PP250019	Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas	Argenbright, Keith	The University of Texas Southwestern Medical Center	3.1	$1,499,243
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services					

Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas proposes leverage the existing cancer screening framework including community outreach and health promotion, comprehensive lung cancer screening with nurse-driven clinical navigation through follow-up and treatment where appropriate, supported by tobacco cessation education and counseling and education, and centralized reimbursement for local providers to support patients who are either uninsured or underinsured. This evidence-based program will bring lung cancer screening into real-world settings across 36 rural and underserved counties in East Texas. Providers identified through targeted community outreach will refer screen-eligible patients to the program following shared decision-making. These patients will then receive lung cancer screening supported by telephone-based navigation, with tobacco cessation education counseling being offered to patients who are active smokers. The program team will facilitate care linkage, with services provided by regional clinical partners. The proposed program will provide multilevel support to ensure the completion of the lung cancer screening process, up to and including the start of treatment. A patient-centered approach to quality metrics will standardize the evaluation approach, allowing for comparisons between organ sites and identifying potential intervention points within the screening process to support the optimization of delivery and improve screening process outcomes.

PP240046	The Houston Prevenir, Ayudar, Poder (PAP) Project	Zamorano, Abigail	The University of Texas Health Science Center at Houston	3.6	$1,499,997
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services					

The proposed Houston Prevenir, Ayudar, Poder (PAP) Project provides cervical cancer screening, diagnosis, and treatment of precancer/dysplasia through colposcopy and LEEP (Loop Electrosurgical

Excisional Procedure). The underserved Hispanic population is at remarkably high risk for cervical cancer and has the lowest adherence rates of follow-up after abnormal screening. The project will meet the needs of this underserved population with accessible specialty services and education in medically underserved areas (MUAs) of the greater Houston area, including Harris and all surrounding counties, to provide increased access to cervical dysplasia diagnosis and treatment, and to build an educational and counseling model for colposcopy and LEEP. High-valueeducation and counseling will be delivered by peer health advocates, thereby increasing follow up of abnormal cervical cancer screening, increasing the diagnosis and treatment of cervical dysplasia, and preventing more cervical cancers. These interventions will build on other CPRIT-funded programs that provide cervical cancer screening to maximize the impact.

PP250004	A Virtual, Centralized Lung Cancer Screening Program for Northeast Texas	Minnix, Jennifer	The University of Texas M. D. Anderson Cancer Center	3.7	$1,497,342
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services					

The aim of this project is to increase access to and completion of lung cancer screening (LCS) services for persons who reside in Texas Public Health Region 4/5N and are at high risk of lung cancer due to past or present cigarette use by implementing a centralized LCS program. These programs are highly effective in providing cessation services for patients who smoke, have better follow-up care for patients who have abnormal findings on low-dose computed tomography, and patients seen in these programs are more adherent to annual screening compared to patients from de-centralized programs. Key features of centralized LCS programs such as this are reliance of primary care clinicians to identify and refer patients eligible for screening, provision of smoking cessation and shared decision making by trained clinicians, and use of navigators for nodule management, patient tracking and follow-up, and quality improvement. This project will use a virtual, centralized model to deliver high-quality, guideline concordant LCS services through a collaboration between the UT Health East Texas, the largest provider of LCS services in NE Texas, and the MD Anderson Cancer Center's Tobacco Quitline and Decision Support Lab. By leveraging existing, complementary strengths of these institutions, a novel program will be implemented to deliver well-established, evidence-based clinical services to persons who meet eligibility criteria and are at greatest risk for developing and dying from lung cancer due to cigarette exposure.

PP250009	The Central Texas Colorectal Cancer Screening Program (CTX-CCSP)	Shokar, Navkiran	The University of Texas at Austin	3.8	$2,500,000
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services					

The Central Texas Colorectal Cancer Screening Program (CTX-CCSP) proposes to comprehensively address colorectal cancer prevention and early detection in a nine-county area of Central Texas located

within Public Health Region 7. The CTX-CCSP has been shown to be effective and cost effective in improving screening completion among vulnerable individuals. The comprehensive multimodal program comprises no-cost screening, diagnostic services and patient navigation and is designed specifically to address the barriers experienced by individuals in this region. Program components include a clinic-wide mail out of fecal immunochemical test kits (FITs) to eligible individuals, education and dedicated bilingual navigation to ensure completion of care pathways to diagnostic colonoscopy and treatment if there is a cancer diagnosis. The project proposes to expand access and maximize impact through increased reach and effectiveness with data driven approaches. The new partners serve populations experiencing disparities such as safety-net populations, African Americans, refugee populations, recent immigrants and the uninsured.

PP250005	Project 80% Colorectal Cancer Screening Program	Foxhall, Lewis	The University of Texas M. D. Anderson Cancer Center	4.2	$2,499,990
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services					

The proposed "Project 80%" aims to reduce colorectal cancer morbidity and mortality and promote earlier detection of colorectal cancer (CRC) among uninsured and low-income patients by partnering with Federally Qualified Health Centers (FQHCs) and other non-profit community clinics in rural and urban health professional shortage areas of Texas. This expansion will expand from 51 to 64 counties. The program is a multi-component intervention implemented at the patient-, clinic- and system level. Project 80% addresses common barriers to CRC screening such as cost and accessibility. Strategies include patient reminders; individual and group education; provider reminders, feedback and assessment; and reduction of structural barriers and patient costs. Project 80% offers an initial Fecal Immunochemical Test (FIT) to eligible patients ages 45-75 or direct referrals to colonoscopy for those at increased risk due to a personal history of adenomas or CRC or family history Clinic patients with abnormal (positive) FIT results are referred to a community endoscopy provider for colonoscopy and polypectomy, if needed, at no cost to the patient for the clinical services. Surveillance colonoscopy is also provided per physician recommendations. Patients diagnosed with colorectal cancer are navigated into treatment.

Primary Prevention of Cancer

Mechanism:

This award mechanism focuses on increasing implementation of evidence-based strategies to ensure that all Texans benefit from the cancer prevention knowledge that we currently have. CPRIT seeks to fund multilevel interventions to reduce cancer risk, disease burden, and cancer disparities. Modifiable risk behaviors include tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, sun exposure, HPV vaccination, Hepatitis B vaccination, and environmental/ occupational cancer exposures. Applications should also assess and address social determinants that contribute to cancer burden and disparities (e.g., cultural factors, unmet needs, access barriers). Interventions and communications should be structured to address the unique circumstances of the population to be served.

Award: Maximum of $1M for new projects and $2.5M for expansion projects; maximum duration of 5 years

Recommended project (1): $1,000,000

Six applications were submitted in this mechanism. One *Primary Prevention of Cancer* application is recommended.

Project Description

PP250016	Screening and treatment for unhealthy alcohol use for cancer prevention in Central Texas - 2	Calderon-Mora, Jessica	The University of Texas at Austin	3.4	$1,000,000
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services					

This project proposes to incorporate an outpatient unhealthy alcohol use screening and intervention program to address the burden of alcohol-related cancers. Primary care patients, 18 years and older, at CommUnity Care Health Centers and Lone Star Circle of Care, both FQHC systems with multiple clinic sites in Central Texas, will be screened using the Alcohol Use Disorder Identification Test – Concise (AUDIT-C). Those who screen positive will be referred to interventionists who will provide a behavioral intervention incorporating motivational interview techniques tailored to the needs of the patient. Patients who are willing to reduce their alcohol consumption will be guided in establishing 1-2 short-term goals with the interventionist and be counseled on the link between alcohol and cancer. The interventionist will also assess patients for current tobacco use and need for cancer screening. The patient will be referred to existing CPRIT-funded prevention programs that can provide smoking cessation resources, breast, and colorectal cancer screenings.

Dissemination of CPRIT-Funded Cancer Control Interventions

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

Award: Maximum of $450,000; maximum duration of 3 years

Recommended project (1): $449,929

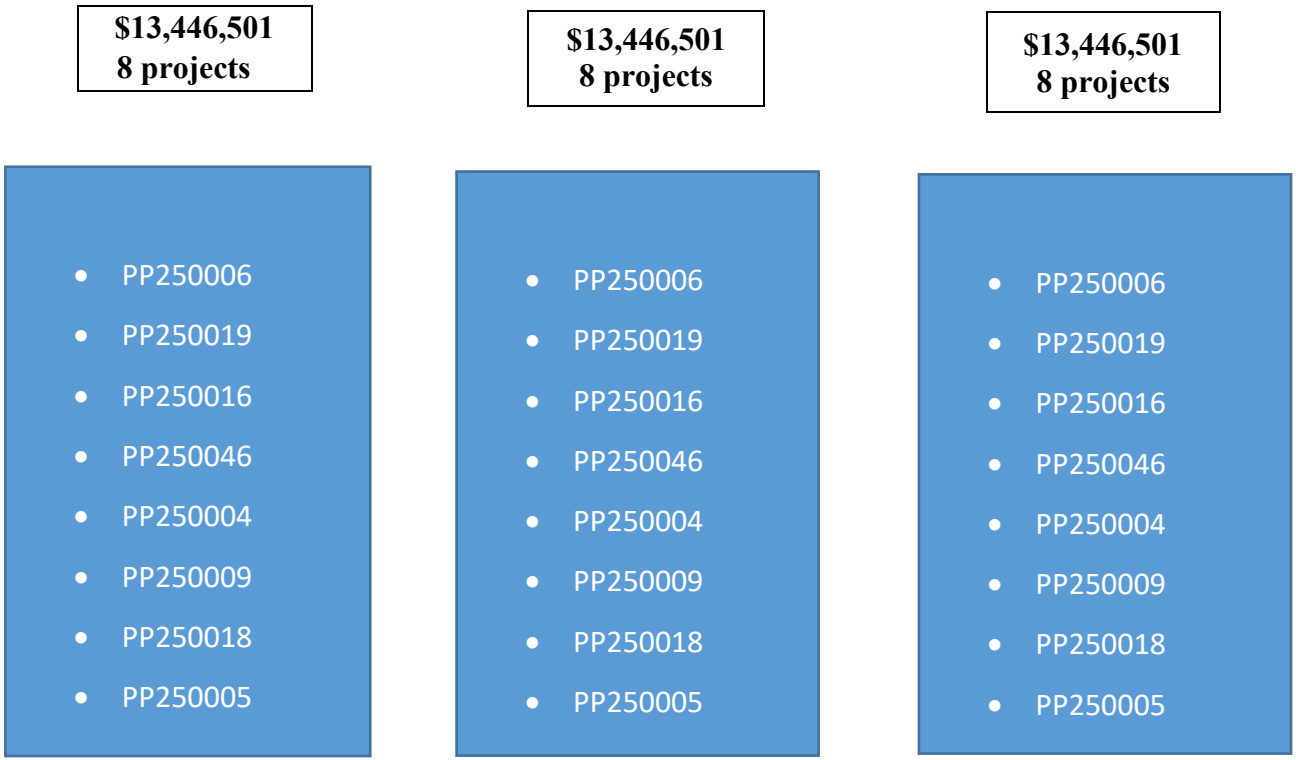
One application was submitted in this mechanism. One *Dissemination of CPRIT-Funded Cancer Control Interventions* application is recommended.

Project Description

PP250018	Texas Comprehensive Access & Resources for Early Detection Lung Cancer	Zoorob, Roger	Baylor College of Medicine	3.8	$499,929
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services					

This project proposes to develop an evidence-informed blueprint, implementation guide, web-based education modules, and consultation service for expanding referral and access to low-dose CT scan (LDCT) screening to eligible patients in underserved areas of Texas, in cooperation with other Texas institutions and community groups. Active dissemination of a successful LDCT screening program that has achieved success at improving outreach among underserved communities in both urban and rural communities may be achieved through education, training, and outreach among primary care clinicians across Texas. The TEX-CARE education course will include an interactive website and toolkit that will provide primary care clinicians with key information on implementing LC screening in their practice and provide guides on strategies for patient follow-up. Web-based education modules will include active learning strategies that will engage practicing clinicians in activities that are developed to: 1) improve their confidence in implementing identification of eligible patients according to current guidelines, 2) include strategies to effectively educate, refer, and follow-up with patients for LDCTs, and 3) instruct clinicians on providing evidence-based smoking cessation services.

Prevention Program Priorities Addressed by Recommended Awards November 20, 2024			
Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence	**Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence**	**Prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services**	**Prevention Program Assessment**



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

Dr. David Cummings
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dcummingsmd@yahoo.com

Kristen Doyle
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to kdoyle@cprit.texas.gov

Dear Dr. Cummings and Ms. Doyle,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for the FY2025 Cycle 1 Cancer Screening and Early Detection (CSD), Primary Prevention of Cancer (PPC), and Dissemination of CPRIT-Funded Cancer Control Interventions (DI) grant awards.

The PRC met on October 18, 2024, to consider the applications recommended by the peer review panel following their September 10 -11, 2024, meeting. The PRC recommends 8 projects totaling $13,446,501.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The average score for recommended applications ranges from 2.7 to 4.2, with an average score of 3.54. The PRC made no changes to the goals, project objectives, or timelines of the applications.

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

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

Attachment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cycle 25.1 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP250006	CSD	Expansion of Cancer Screening and Early Detection Services to Rural & Medically Underserved Communities	Duckworth, Jessica	The Rose	2.7	1	$2,500,000
PP250019	CSD	Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas	Argenbright, Keith	The University of Texas Southwestern Medical Center	3.1	2	$1,499,243
PP250016	PPC	Screening and treatment for unhealthy alcohol use for cancer prevention in Central Texas – 2	Calderon-Mora, Jessica	The University of Texas at Austin	3.4	3	$1,000,000
PP250046	CSD	The Houston Prevenir, Ayudar, Poder (PAP) Project	Zamorano, Abigail	The University of Texas Health Science Center at Houston	3.6	4	$1,499,997
PP250004	CSD	A Virtual, Centralized Lung Cancer Screening Program for Northeast Texas	Minnix, Jennifer	The University of Texas M. D. Anderson Cancer Center	3.7	5	$1,497,342
PP250009	CSD	The Central Texas Colorectal Cancer Screening Program (CTX-CCSP)	Shokar, Navkiran	The University of Texas at Austin	3.8	6	$2,500,000
PP250018	DI	Texas Comprehensive Access & Resources for Early Lung Cancer Prevention (TEX-CARE)	Zoorob, Roger	Baylor College of Medicine	3.8	7	$449,929
PP250005	CSD	Project 80% Colorectal Cancer Screening Program	Foxhall, Lewis	The University of Texas M. D. Anderson Cancer Center	4.2	8	$2,499,990

CSD: Cancer Screening and Early Detection
PPC: Primary Prevention of Cancer
DI: Dissemination of CPRIT-Funded Cancer Control Interventions

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE
From: KEN SMITH, PHD, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject: FY 25.1 PRODUCT DEVELOPMENT RESEARCH AWARD RECOMMENDATIONS
Date: NOVEMBER 20, 2024

Summary of Recommendation:

The Product Development Review Council (PDRC) recommends that the Program Integration Committee (PIC) and the Oversight Committee approve product development research awards to the following applicants: Curve Biosciences, Marker Therapeutics, Inc., Telos Biotechnology, Metaclipse Therapeutics Corporation, Barricade Therapeutics, Corp., Ypsilon Therapeutics, Orphagen Pharmaceuticals, Inc., Eisbach Bio Inc., and Erisyon, Inc. The table below reflects the ranked award recommendations, including the maximum recommended funding amounts and the evaluation scores for the nine applications recommended for awards.

CPRIT CEO Kristen Doyle granted me a communication waiver pursuant to T.A.C. section 702.19(e) to communicate with companies directly about the substance of their pending applications as part of the budget and contract pre-award negotiations. The recommendations contain no contingencies, and I have been working with all 9 companies recommended for funding to negotiate budget reductions, and the proposed budgets will be updated during our upcoming meeting.

FY 2025 Cycle 1 Award Recommendations

Rank	ID	RFA	Company	Project	Score *	Budget
1	DP250157	TDDCFULL	Curve Biosciences	Clinical Utility Study for the Commercial Launch of a Best-in-Class Liver Cancer Screening Blood Test for High-Risk Liver Disease Patients	1.9	$11,340,000
2	DP250150	TTCFULL	Marker Therapeutics, Inc.	A Phase 1 Study of Multi-Tumor Associated Antigen Specific T Cells (MT-601) in Patients with Metastatic Pancreatic Cancer following frontline FOLFIRINOX	2.1	$9,513,569
3	DP250143	SEED Tech	Telos Biotechnology	TELOVANCE: A Transient Telomere Lengthening Platform Designed to Enhance the Expansion and Efficacy of Human Cell and Gene Therapies	2.3	$2,778,945
	DP250135	TTCFULL	Metaclipse Therapeutics Corporation	Personalized Immunotherapy for Recurrent, Resectable Head and Neck Cancer	2.4	$6,080,245
5	DP250159	TTCFULL	Barricade Therapeutics, Corp.	(S)-TASIN-15 Phase 1 Dose Escalation, Optimization & RP2D Determination	2.4	$14,005,035
6	DP250137	SEED Therapeutics	Ypsilon Therapeutics	Revolutionizing Solid Tumor Therapy with Bispecific TCRm Antibodies Targeting Intracellular Cancer Targets	2.5	$2,727,500

Rank	ID	RFA	Company	Project	Score *	Budget
7	DP250140	TTCFULL	Orphagen Pharmaceuticals, Inc.	A Phase 1 clinical trial of OR-449, a novel oral targeted therapy for pediatric and adult adrenocortical cancer patients	2.6	$10,213,909
8	DP250142	TTCFULL	Eisbach Bio Inc.	Eisbach Bio - Clinical Development of the ALC1 DDR inhibitor EIS-12656	2.7	$4,750,000
9	DP250149	SEED MD&D	Erisyon, INC	Functional assay of immunoproteasome for patient stratification to checkpoint inhibitor therapy using single-molecule protein sequencing	2.8	$2,157,173
					TOTAL	$63,566,376

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

Background - FY 2025 Review Cycle 1

CPRIT released four FY 2025 Product Development Research RFAs on April 15th and opened the portal to receive preliminary applications on April 22nd. By the May 1st deadline, CPRIT had received 90 preliminary applications, including submissions from 32 companies located outside Texas in states such as Massachusetts, California, Georgia, Pennsylvania, New Jersey, Florida, Michigan, Oregon, Delaware, Iowa, New Mexico, and Arizona, as well as from South Korea, Israel, and Germany. Based on preliminary review panel decisions, 24 companies were invited to submit full applications, and we received 22 full applications by the July 25th deadline, requesting a total funding of $181,109,160. Nine projects advanced to due diligence after full application review, with a combined request of $68,863,933. Texas Therapeutic Company (TTC) led with 9 applications reviewed, 5 progressing to due diligence, and a due diligence request of $48,024,636. Texas Diagnostic Development Company (TDDC) had 5 applications reviewed, with 1 advancing, requesting $12,600,000. Seed funding saw 6 applications reviewed, with 3 advancing to due diligence, requesting $8,239,297. The total requested budget after due diligence for all mechanisms is $68,863,933.

Following further review, the PDRC convened October 28th and finalized ranking and funding recommendations for nine projects. The recommended awards include projects with a total negotiated budget of $63,566,376.

Product Development Research Priorities Addressed by the 25.1 Cycle Proposed Awards

The chart below shows 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*
9	Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies	**$63,566,376**
9	Funding projects addressing large or challenging unmet medical needs	**$63,566,376**

6	Investing in early-stage projects where private capital is least available	**$45,245,061**
5	Stimulating commercialization of technologies developed at Texas institutions	**$27,391,096**
6	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	**$45,815,389**
9	Providing appropriate return on taxpayer investment	**$63,566,376**

*Some proposed awards address more than one priority.

Mechanism of Support and Product Development Research Objectives

Applications submitted in the 25.1 review cycle responded to one of four product development research RFAs.

- *Texas Therapeutic Company Award (TTC)*

  This award mechanism seeks to support the companies that have identified and characterized a lead compound; demonstrated efficacy in multiple translationally relevant animal models; completed pilot/dose-ranging toxicology studies; determined the feasibility of a scalable, GMP-compliant manufacturing process, including release assays; and identified a prototype formulation suitable for further development. The applicant is typically within 1 year from filing an IND/IDE or already in phase 1.

  Award: Uncapped amount over 36 months

- *Texas Device and Diagnostics Company Award (TDDC)*

  This award mechanism seeks to support the ongoing research and development of diagnostic tests and devices to treat, detect, diagnose, monitor, and assist in the treatment of cancer. Generally, at the time that an applicant applies to CPRIT pursuant to this RFA, the company has developed a commercial prototype of the device or a pictorial representation of the functional components/elements of the device. With respect to diagnostics, the company has developed assays that work on human samples and whose importance is well justified for development into clinical assays. The applicant should be working toward submitting an Investigational Device Exemption (IDE) or a 501(k) or Premarketing Approval (PMA) and is typically within 1 year from filing an IDE (or later stage work.)

Award: Uncapped amount over 36 months

- *Texas New Technologies Company Award (TNTC)*

This award mechanism seeks to support the ongoing research and development of new and emerging technologies for the detection, diagnosis, prognosis, monitoring, or treatment of cancer. Proposals may include bioinformatics, artificial intelligence, production of radionuclides or their precursors, manufacture of cell-based therapies, processes to improve the quality of the samples used for cancer research or clinical care, and biomanufacturing of therapeutics.

Award: Uncapped amount over 36 months

- *Texas Seed Company Award* (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 be headquartered in Texas or be willing to relocate to Texas upon receipt of the 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.

Product Development Research Awards
Recommended by the PDRC for FY 2025 Review Cycle 1

Curve Biosciences
Proposed TDDC FULL Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Device and Diagnostics Company Award Full Award for Product Development Research to Curve Biosciences for $11,340,000.

Curve Biosciences, relocating its headquarters from Mountain View, CA, to Dallas, TX, is conducting a clinical utility study on a blood test designed for early detection of liver cancer in high-risk patients. This study will assess the accuracy of Curve's blood test in detecting liver, bile duct, and gallbladder cancers among 2,000 high-risk liver disease patients, compared to the current standard-of-care. The study's results are intended to support potential insurance coverage and broader use by healthcare providers, addressing liver cancer rates associated with the obesity epidemic, particularly in Texas.

CPRIT Product Development Research Priorities Addressed

Curve Biosciences' proposed project addresses five of the six Product Development Research Priorities:

- Providing appropriate return on Texas taxpayer investment
- Funding novel projects that offer therapeutic or diagnostic benefits, i.e. disruptive technologies
- Funding projects addressing large or challenging unmet medical needs
- Investing in early-stage projects where private capital is least available
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff

Project Summary and Scientific Rationale

Curve Biosciences is developing a blood-based assay, the Curve Test, aimed at enhancing early detection of hepatocellular carcinoma (HCC) in high-risk populations. The current standard of care (SOC) for HCC, which includes ultrasound imaging and alpha-fetoprotein testing, detects only 33% of early HCC cases due to challenges in patient compliance and limited sensitivity for small tumors. The Curve Test addresses this gap by using specific biological markers unique to HCC, thus improving early detection accuracy.

The innovation behind the Curve Test is powered by Curve's Whole-Body Tissue Atlas (WBTA), a database of over 400,000 samples from various tissue types, which enables precise identification of HCC-specific biomarkers. By distinguishing HCC markers from unrelated biological signals, the Curve Test can detect early-stage HCC with 84% sensitivity—significantly outperforming current SOC. This improvement could boost the five-year survival rate from 27% to 52%, representing a major advance in patient outcomes and offering substantial cost savings for insurers.

To support commercialization, Curve plans three studies: an 800-patient trial for regulatory clearance, a 2000-patient utility study comparing Curve Test with SOC, and a 3000-patient pilot

study to capture ordering behaviors and support broader insurance adoption. These studies aim to solidify Curve Test's role as a superior HCC detection method and to drive widespread insurance coverage.

CPRIT funding will be instrumental in advancing the Curve Test, accelerating Curve's timeline to market and facilitating the company's significant Texas-based operational expansion. The award would also support the establishment of a headquarters, clinical lab, and Texas-based collaborations, positioning Texas as a leader in diagnostic advancements for liver cancer.

Select Reviewer Comments

"The management team is very strong, bringing in high-level people from well-respected institutions like Genentech, GRAIL, and Stanford University. This reviewer has no concerns about the leadership team."

"This proposal contains very strong preliminary data. Specifically, they performed a blinded, multi-site study involving 194 patients that were at high risk for liver cancer, tested using the Curve assay against a gold standard (MRI), with results showing 95% sensitivity and 96% specificity."

"The market opportunity here appears strong, with a projected market size of over $10B in the U.S. for surveilling high-risk liver disease patients. Interviews with target physicians indicate that 92% are willing to order this new test if it can be reimbursed."

Marker Therapeutics, Inc.
Proposed TTC FULL Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Full Award for Product Development Research to Marker Therapeutics for $9,513,569.

Marker Therapeutics, based in Houston, TX, is conducting a Phase 1 clinical study to evaluate its therapy, MT-601, in patients with metastatic pancreatic cancer (mPC) following frontline treatment with FOLFIRINOX. MT-601 is an autologous polyclonal T-cell therapy designed to target multiple tumor-associated antigens. This study will assess the therapy's safety and efficacy when combined with standard chemotherapy. The CPRIT funding will support efforts to enhance immune response in mPC patients, with MT-601 utilizing the patient's own immune cells to potentially improve treatment outcomes.

CPRIT Product Development Research Priorities Addressed

Marker Therapeutics, Inc.'s proposed project addresses three of the six Product Development Research Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits, i.e. disruptive technologies
- Funding projects addressing large or challenging unmet medical needs
- Stimulating commercialization of technologies developed at Texas entities

Project Summary and Scientific Rationale

Marker Therapeutics is advancing MT-601, a T cell therapy for metastatic pancreatic cancer (mPC), leveraging six tumor-associated antigens (mTAA) highly expressed in pancreatic cancer to reduce tumor escape and off-target effects. MT-601 is designed for outpatient administration, enhancing accessibility while minimizing toxicity, and has shown promising efficacy in lymphoma, with early pancreatic cancer trials indicating robust safety and initial efficacy.

MT-601's unique targeting mechanism allows it to recognize and kill tumor cells through native T cell receptors, addressing a critical need for more effective mPC treatments. Only 52% of patients are eligible for standard mPC chemotherapy due to high toxicity, making MT-601's non-toxic approach particularly valuable. The therapy's design avoids genetic engineering, providing a novel, safer immunotherapy alternative.

Marker's Phase 1 trial will assess MT-601 with FOLFIRINOX in mPC patients across multiple sites, including MD Anderson Cancer Center (MDACC). A dose-escalation phase and dose expansion cohort will evaluate safety and efficacy, with results supporting applications for Regenerative Medicine Advanced Therapy (RMAT) designation and facilitating progression to larger trials.

With CPRIT funding, Marker Therapeutics can advance MT-601 through clinical trials while expanding partnerships with Texas-based entities, supporting Texas's healthcare landscape with cutting-edge mPC treatments. The funding will expedite MT-601's path to market, offering new hope for patients with limited therapeutic options.

Select Reviewer Comments

"Given the unmet medical need of pancreatic cancer, the intended product will significantly address the treatment of this cancer."

"The company has obtained FDA orphan drug designation for MT-601 in treating metastatic pancreatic cancer, and preliminary clinical data show promising safety and efficacy."

"MT-601's target patient population, current clinical stage of development, excellent safety profile, potential for increased efficacy, and lack of genetic engineering gives MT-601 a considerable edge in the market."

Telos Biotechnology
Proposed SEED Tech Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Technology Company SEED Award for Product Development Research to Telos Biotechnology for $2,778,945.

Based in Dallas, TX, Telos Biotechnology is developing TELOVANCE, a platform designed to temporarily lengthen telomeres to enhance human cell and gene therapies. This funding will support the manufacturing of TELOVANCE in Texas and its integration into CAR T-cell production processes. The grant will also fund studies on the platform's safety and efficacy in animal models and explore its potential applications in therapies for lymphoma, myeloma, and melanoma.

CPRIT Product Development Research Priorities Addressed

Telos Biotechnology's proposed project addresses all six of the 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
- 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 taxpayer investment

Project Summary and Scientific Rationale

Telos Biotechnology aims to improve CAR T-cell therapy outcomes with TELOVANCE, a telomerase-based treatment that extends telomeres during CAR T-cell manufacturing to delay cell senescence and enhance efficacy. As telomere shortening limits CAR T-cell longevity, TELOVANCE addresses this challenge by selectively extending telomeres in CAR T-cells, improving their therapeutic potential without risk of immortalization.

TELOVANCE's transient telomere extension increases cell survival and cytotoxicity, tackling a key limitation in CAR T-cell therapies, where only 50% of patients achieve long-term remission. This innovation, validated in both in-vitro and in-vivo studies, is positioned to transform CAR T-cell therapy by boosting the performance and durability of the manufactured cells.

The project will transition TELOVANCE production to GMP standards and conduct in-vivo studies for expanded safety testing. Additional studies will explore TELOVANCE's potential in other cell types, expanding its applications beyond hematologic cancers.

CPRIT support will allow Telos to advance TELOVANCE toward commercial readiness and enhance Texas's biotech ecosystem. By establishing a manufacturing presence in Texas, Telos can drive cell therapy innovations and create economic impact through high-value therapeutic developments.

Select Reviewer Comments

"The lack of significant long-term responses in many CAR-T treated patients is a genuine unmet medical need, and Telos is positioned to potentially improve and increase those long-term responses."

"Telovance-treated CAR T-cells showed an increase in persistence six months after injection into mice during pilot safety studies. This is a critically important and clinically relevant result."

"The application proposes the development of an innovative technology that could potentially impact the treatment of cancer and benefit cancer patients greatly. The applicants explain the unique role of Telovance in that it improves the efficacy and durability of cell and gene therapies."

Metaclipse Therapeutics Corporation
Proposed TTC FULL Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Full Award for Product Development Research to Metaclipse Therapeutics for $6,080,245.

Metaclipse Therapeutics, relocating its headquarters from Atlanta, GA, to Houston, TX, is developing Membrex, a personalized cancer vaccine designed for recurrent, resectable head and neck squamous cell carcinoma (HNSCC). This funding will support a Phase 1a/b clinical trial at MD Anderson to assess Membrex, which uses patient-specific tumor vesicles with immunostimulatory proteins to activate the immune system, with the goal of preventing

recurrence and metastasis. The relocation will facilitate local collaborations and support scaled production in Texas, aligning with CPRIT's objectives to advance innovative cancer treatments.

CPRIT Product Development Research Priorities Addressed

Metaclipse Therapeutics Corporation'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
- 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 taxpayer investment

Project Summary and Scientific Rationale

Metaclipse's Membrex vaccine, a personalized autologous immunotherapy, seeks to improve immune responses in head and neck squamous cell carcinoma (HNSCC) by overcoming resistance to immune checkpoint inhibitors (ICIs). Using tumor membrane vesicles (TMVs) from patient tumor tissue, Membrex combines tumor-specific antigens with potent immunostimulatory molecules to induce a more robust T-cell response.

Preclinical studies in HNSCC models have demonstrated Membrex's efficacy, showing increased T-cell infiltration, tumor growth reduction, and metastasis prevention. By sensitizing tumors to anti-PD-1 therapy, Membrex could extend the benefits of ICIs to a broader range of HNSCC patients who currently lack durable responses.

The Phase 1a/b clinical trial will assess Membrex's safety and efficacy in combination with ICIs, conducted at MDACC and additional Texas-based sites. GMP manufacturing will be supported by Texas-based CDMO Fujifilm Diosynth, ensuring operational continuity in the state.

CPRIT funding will enable Metaclipse to advance Membrex in Texas, establishing a base in Houston to drive clinical and operational growth. This support will boost Texas's role in personalized immunotherapy, advancing treatment options for HNSCC patients while fostering economic development.

Select Reviewer Comments

"Membrex vaccine immunotherapy has the potential to significantly address an unmet medical need in the treatment of recurrent HNSCC."

"The successful completion of the goals and objectives of this project will allow go / no-go decisions to be made about further clinical and product development, with strong potential for new drug products that can address current unmet medical needs."

"Membrex is poised to exercise one of many business strategies upon obtaining convincing clinical data in their Phase 2 study."

Barricade Therapeutics, Corp.
Proposed TTC FULL Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Full Award for Product Development Research to Barricade Therapeutics, Corp. for $14,005,035.

Headquartered in Dallas, TX, Barricade Therapeutics, Corp. is advancing TASIN-15, a small molecule therapeutic specifically designed for colorectal cancer (CRC) patients with a mutation in the adenomatous polyposis coli (APCmut) gene, found in 80% of CRC cases. This funding will support Phase 1 clinical trials, set to begin in the first half of 2025, focusing on dose escalation, optimization, and determining a recommended Phase 2 dose (RP2D). The trials aim to build on promising animal study results and establish a safe and effective dose, potentially offering a targeted therapeutic alternative to conventional chemotherapy for CRC patients.

CPRIT Product Development Research Priorities Addressed

Barricade Therapeutics, Corp.'s proposed project addresses five of the six Product Development Research Priorities:

- Providing appropriate return on Texas taxpayer investment
- Funding novel projects that offer therapeutic or diagnostic benefits, i.e. disruptive technologies
- Funding projects addressing large or challenging unmet medical needs
- Stimulating commercialization of technologies developed at Texas entities
- 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

Project Summary and Scientific Rationale

Barricade Therapeutics is developing TASIN-15, a novel therapy targeting the APC mutation (APCmut) prevalent in colorectal cancer (CRC), which is linked to cancer progression. TASIN-15 selectively inhibits Emopamil binding protein (EBP) with minimal off-target effects, offering a new therapeutic approach for advanced CRC patients.

With an 11% survival rate for metastatic CRC (mCRC), TASIN-15 presents a potential breakthrough by improving efficacy where standard therapies fall short. Preclinical studies show TASIN-15's favorable bioavailability, tissue penetration, and safety, paving the way for Phase 1 trials to establish dosage and efficacy.

Barricade seeks CPRIT funding to complete Phase 1 trials in advanced APCmut CRC patients, establishing TASIN-15's potential as a single-agent and combination therapy. The funding will also support Phase 1b expansion to assess broader therapeutic applications.

With CPRIT support, Barricade will demonstrate Texas's capacity for innovative cancer therapy, positioning TASIN-15 as a leading CRC treatment and strengthening Texas's biotech landscape through advanced clinical development.

Select Reviewer Comments

"Advanced colorectal cancer has a very poor 5-year survival rate. There are few effective, targeted treatments for these patients… A novel, targeted oral treatment would be a welcomed treatment option."

"If TASIN-15 is proven to be safe and effective in CRC, this new therapy would be an important step forward in treating this cancer."

"This therapeutic approach could offer a significant contribution to the management of colorectal cancer."

Ypsilon Therapeutics
Proposed SEED Therapeutics Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company SEED Award for Product Development Research to Ypsilon for $2,727,500.

Ypsilon, relocating its headquarters from Waltham, MA, to Houston, TX, is advancing a bispecific TCRm CD3 engager-based immunotherapy targeting the CT83 antigen, which is expressed in several difficult-to-treat cancers, including breast, lung, bronchus, and stomach cancers. This funding will accelerate the development of Ypsilon's CT83-targeted therapy, with a focus on improving its safety and efficacy for solid tumors. The relocation to Texas will contribute to the local biotech ecosystem and aim to provide new treatment options for patients with limited alternatives.

CPRIT Product Development Research Priorities Addressed

Ypsilon Therapeutics' proposed project addresses all six of 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
- 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 taxpayer investment

Project Summary and Scientific Rationale

Ypsilon Therapeutics is advancing TCR mimic (TCRm) x CD3 antibodies targeting the CT83 peptide, selectively expressed in various solid tumors, to overcome limitations in immune checkpoint inhibitor efficacy. This novel immunotherapy directs T cells to specifically target CT83-expressing tumor cells, enhancing safety and precision.

Leveraging Alloy Therapeutics' TCR discovery platform, Ypsilon has developed TCRm antibodies with high affinity for CT83, engineering them into bispecific CD3 T cell engagers. This approach selectively targets malignant tissues, addressing the unmet need in solid tumor treatment.

This project will develop and validate the TCRm CD3 engagers through bispecific engineering and in-vivo studies in xenograft models, with CPRIT support accelerating preclinical milestones. The project will also facilitate Ypsilon's move to Houston, where they plan to collaborate with MDACC.

CPRIT funding will enable Ypsilon to advance this promising treatment, positioning Texas as a leader in solid tumor immunotherapy and providing new options for patients resistant to existing therapies.

Select Reviewer Comments

"Despite advancements in anti-cancer therapies... the prognosis for patients with solid tumors... continues to be poor. Addressing this need is indeed urgently needed."

"If successful, Ypsilon's bispecific TCRm T cell engager may have a meaningful impact in addressing unmet need. The technologies that result in the first drug could be leveraged to make other engagers that address other HLA and other antigens."

"This proposal, if successful, will result in an innovative product that addresses unmet needs in multiple solid cancers. The upside is significant, and the team is as well-suited to successful execution as any small group could be."

Orphagen Pharmaceuticals, Inc.
Proposed TTC FULL Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Full Award for Product Development Research to Orphagen for $10,213,909.

Orphagen, planning to relocate its headquarters from San Diego, CA, to either Austin or Houston, TX, is advancing OR-449, a novel oral small molecule inhibitor targeting adrenocortical carcinoma (ACC). This funding will support a Phase 1 clinical trial at MD Anderson to evaluate the safety and efficacy of OR-449 in treating ACC, with additional potential applications for head and neck and lung squamous carcinomas. Positive results from this trial could enhance survival rates for ACC patients and contribute to establishing Orphagen as a key biotech player in Texas.

CPRIT Product Development Research Priorities Addressed

Orphagen Pharmaceuticals, Inc.'s proposed project addresses five of the six Product Development Research Priorities:

- Providing appropriate return on Texas taxpayer investment
- Funding novel projects that offer therapeutic or diagnostic benefits, i.e. disruptive technologies
- Funding projects addressing large or challenging unmet medical needs
- Investing in early-stage projects where private capital is least available
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff

Project Summary and Scientific Rationale

Orphagen Pharmaceuticals is developing OR-449, a small molecule antagonist targeting steroidogenic factor-1 (SF-1) for treating adrenocortical carcinoma (ACC). SF-1 is highly expressed in ACC and some head and neck and lung squamous carcinomas, with preclinical studies demonstrating OR-449's efficacy in inhibiting tumor growth.

OR-449 is designed to reduce reliance on existing ACC treatments, which have limited success rates. Preclinical toxicology studies have shown no adverse effects, supporting OR-449's advancement into clinical trials for ACC, where options are currently limited.

Orphagen's project aims to complete a Phase 1 clinical trial, exploring dosage and efficacy in adult and pediatric ACC patients. CPRIT funding will support site activation, interim analyses, and manufacturing necessary for the trial's success.

With CPRIT's support, Orphagen will establish its Texas presence, advancing OR-449 as a first-in-class ACC therapy and reinforcing Texas's role in developing rare cancer treatments.

Select Reviewer Comments

"ACC is a rare cancer with severe outcomes in later-stage disease. If this product proves effective, it could provide a significant improvement over the current standard of care for patients with advanced ACC who face limited treatment options."

"OR-449 is a first-in-class inhibitor of SF-1, a novel target for the treatment of ACC... If successful, this drug has the potential to be a breakthrough therapy for both pediatric and adult ACC patients."

"OR-449 has demonstrated considerable preclinical efficacy... The FDA's rare pediatric disease designation for OR-449 and feedback from the pre-IND meeting provide a positive regulatory pathway for advancing this promising candidate."

Eisbach Bio Inc.
Proposed TTC FULL Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Full Award for Product Development Research to Eisbach Bio for $4,750,000.

Eisbach Bio, relocating from Germany to Houston, TX, is advancing EIS-12656, a small molecule ALC1 inhibitor targeting tumors with BRCA1/2 mutations and other DNA damage repair gene mutations. This funding will support a Phase II clinical trial at MD Anderson, focusing on homologous recombination deficiency (HRD) tumors in patients with BRCA1/2 mutations. The trial will evaluate EIS-12656 as a monotherapy, addressing limitations in existing PARP inhibitors related to toxicity and resistance. The goal is to establish a more effective treatment option for HRD patients in Texas and beyond.

CPRIT Product Development Research Priorities Addressed

Eisbach Bio Inc.'s proposed project addresses two of the six Product Development Research Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits, i.e. disruptive technologies
- Funding projects addressing large or challenging unmet medical needs

Project Summary and Scientific Rationale

Eisbach Bio's EIS-12656, a novel DDR helicase inhibitor, targets ALC1 to treat homologous recombination-deficient (HRD) tumors, offering a safer alternative to PARP inhibitors. This innovation addresses a significant need, particularly in PARPi-resistant and HRD-positive tumors with brain metastases.

Preclinical studies show EIS-12656's robust safety profile and blood-brain barrier penetrance, making it suitable for monotherapy and combination therapies with cPARPi and other agents. The drug's efficacy in HRD contexts highlights its transformative potential in solid tumor treatment.

Supported by a partnership with MDACC, Eisbach Bio will conduct Phase I/II trials, with CPRIT funding supporting dose expansion. Relocating to Texas, Eisbach will strengthen Texas's role in oncology, leveraging collaborations to drive EIS-12656's clinical success.

CPRIT funding will support Eisbach's transformative approach to HRD tumor therapy, positioning Texas as a hub for innovative cancer treatments while expanding clinical options for HRD patients.

Select Reviewer Comments

"EIS-12656 has the potential to be a game-changing therapy for patients suffering from HRD solid tumors... with significant potential to improve outcomes for those who have developed resistance to PARP inhibitors."

"As a first-in-class allosteric inhibitor of ALC1, EIS-12656 represents a novel approach, targeting HRD tumors with potential broad applicability across multiple cancer types."

"EIS-12656 demonstrated a markedly superior toxicity profile in comparison with currently available therapies targeting DDR pathways, and the FDA's clearance of the IND underscores the strength of the preclinical data."

Erisyon, Inc.
Proposed SEED MD&D Therapeutics Award for Product Development

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Texas Medical Device and Diagnostics Company SEED Award for Product Development Research to Erisyon for $2,157,173.

Headquartered in Austin, TX, Erisyon is developing a functional assay using single-molecule protein sequencing technology to identify advanced non-small cell lung cancer (NSCLC) patients who are resistant to immune checkpoint inhibitors (ICIs). This assay measures the PSME4/PSMB10 ratio to gain insights into tumor antigenicity, which could guide patient stratification for checkpoint inhibitor therapy. The CPRIT funding will support the assay's development, with objectives of advancing to clinical trials and pursuing FDA approval to improve patient outcomes and further cancer care innovations in line with CPRIT's mission.

CPRIT Product Development Research Priorities Addressed

Erisyon, Inc.'s proposed project addresses four of the six Product Development Research Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits, 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 entities

Project Summary and Scientific Rationale

Erisyon is developing a fluorosequencing-based assay to predict immune checkpoint inhibitor (ICI) resistance in non-small cell lung cancer (NSCLC) patients. By measuring the PSME4 to PSMB10 ratio in immunoproteasomes, this biomarker can identify treatment-resistant tumors, guiding effective therapy selection.

This innovative assay provides absolute molecular quantitation and high sensitivity, enabling accurate antigenicity assessments. With fluorosequencing's capability, Erisyon addresses limitations in current mass spectrometry and antibody assays, enhancing precision in predicting ICI outcomes.

The project will validate the assay's clinical utility through controlled and patient samples, with benchmarking against FDA-approved assays. CPRIT support will enable Erisyon's scale-up and regulatory compliance activities, advancing toward FDA approval.

CPRIT funding will help Erisyon establish a high-impact diagnostic tool in Texas, supporting oncologists with improved patient stratification tools and furthering Texas's contributions to precision cancer diagnostics.

Select Reviewer Comments

"The applicants target a significant challenge in oncology: the early identification of non-small cell lung cancer (NSCLC) patients likely to benefit from checkpoint inhibitor therapy. ... a newly developed test, in combination with the success of immune checkpoint inhibitors (ICIs), could benefit a substantial number of cancer patients."

"If successful, the project could significantly expand the eligible patient population for ICI therapy and aid in the development of more effective ICI therapies by offering accurate insights into tumor antigenicity."

"By specifically targeting the PSME4/PSMB10 ratio within tumor cells, this product directly indicates the tumor's status and its potential receptivity to ICI therapy, potentially overcoming a significant barrier in the current approach to cancer treatment."

October 29, 2024

Dr. David Cummings
CPRIT Oversight Committee Chair
Via email to dcummingsmd@yahoo.com

Ms. Kristen Pauling Doyle
CPRIT Program Integration Committee Chair
Via email to kdoyle@cprit.texas.gov

Dr. Cummings and Ms. Doyle,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 25.1 grant award cycle. The PDRC convened on October 28, 2024, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Curve Biosciences, Marker Therapeutics, Inc., Telos Biotechnology, Metaclipse Therapeutics Corp., Barricade Therapeutics, Corp., Ypsilon Therapeutics, Orphagen Pharmaceuticals, Inc., Eisbach Bio Inc., and Erisyon Inc. The attached table reflects the ranked award recommendation for the nine (9) grant applications. The recommendations contain no contingency.

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

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Council

CPRIT 25.1 Product Development Research
Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Application Title	Organization	Final Overall Score	Recommended Budget
1	DP250157	TDDC	New	Patnaik, R	Clinical Utility Study for the Commercial Launch of a Best-in-Class Liver Cancer Screening Blood Test for High-Risk Liver Disease Patients	Curve Biosciences	1.9	$ 12,600,000
2	DP250150	TTC	New	Vera, J	A Phase 1 Study of Multi-Tumor Associated Antigen Specific T Cells (MT-601) in Patients with Metastatic Pancreatic Cancer following frontline FOLFIRINOX	Marker Therapeutics, Inc.	2.1	$ 10,226,179
3	DP250143	SEED	Resubmission	Sayed, M	TELOVANCE: A Transient Telomere Lengthening Platform Designed to Enhance the Expansion and Efficacy of Human Cell and Gene Therapies	Telos Biotechnology	2.3	$ 2,998,945
4	DP250135	TTC	Resubmission	Pack, C	Personalized Immunotherapy for Recurrent, Resectable Head and Neck Cancer	Metaclipse Therapeutics Corporation	2.4	$ 6,395,245
5	DP250159	TTC	New	Thapar, N	(S)-TASIN-15 Phase 1 Dose Escalation, Optimization & RP2D Determination	Barricade Therapeutics, Corp.	2.4	$ 15,485,443
6	DP250137	SEED	New	Zha, D	Revolutionizing Solid Tumor Therapy with Bispecific TCRm Antibodies Targeting Intracellular Cancer Targets	Ypsilon Therapeutics	2.5	$ 2,997,500
7	DP250140	TTC	New	Thacher, S	A Phase 1 clinical trial of OR-449, a novel oral targeted therapy for pediatric and adult adrenocortical cancer patients	Orphagen Pharmaceuticals, Inc.	2.6	$ 10,917,769
8	DP250142	TTC	Resubmission	Schomburg, A	Eisbach Bio - Clinical Development of the ALC1 DDR inhibitor EIS-12656	Eisbach Bio Inc.	2.7	$ 5,000,000
9	DP250149	SEED	New	Swaminathan, J	Functional assay of immunoproteasome for patient stratification to checkpoint inhibitor therapy using single-molecule protein sequencing	Erisyon, INC	2.8	$ 2,242,852

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	T.A.C. § 702.19 WAIVER APPROVAL FOR DR. KEN SMITH
DATE:	OCTOBER 29, 2024

Summary

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I have granted Chief Product Development Officer Dr. Ken Smith a waiver from the general prohibition against communicating with a grant applicant while CPRIT is accepting and reviewing applications. The waiver applies to communication with the nine companies that the Product Development Review Council (PDRC) has recommended for grant awards in review cycle 25.1. Approving the waiver promotes CPRIT's objectives and does not give one or more applicants an unfair advantage. No Oversight Committee action related to this waiver is necessary.

Discussion

The Chief Product Development Officer is a statutorily mandated member of the Program Integration Committee (PIC). Texas Administrative Code § 702.19 prohibits substantive communication between the grant applicant and a member of the peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The communication restriction is one way that we prevent even the appearance of unequal treatment in the grant review process. However, the rule provides a process for the CEO to waive the communication restriction in specific circumstances if doing so is in the interest of CPRIT's process and does not give any applicant an unfair advantage.

Approving this waiver allows Dr. Smith to negotiate reductions in proposed budgets with each company prior to Oversight Committee approval. Granting the waiver will not favor any applicant or provide an unfair advantage.

The Oversight Committee does not need to take any action regarding this waiver. Dr. Smith's waiver will be part of the grant record for the FY 2025 product development awards.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

November 15, 2024

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of grant contracts for the nine companies that the Oversight Committee will consider for product development research grant awards at its November 20, 2024, meeting. The Program Integration Committee has recommended these companies for grant awards.

Although CPRIT disburses most grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.02(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 projects proposed for grant awards involve 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 these projects to begin work as quickly as possible.

Sincerely,

Kristen P. Doyle
Chief Executive Officer

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

November 8, 2024

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendation for funding 22 grant applications totaling $89,012,876. I have attached the PIC's recommendations for the five academic research, eight prevention, and nine product development research grant awards.

Chief Scientific Officer Dr. Michelle Le Beau, Chief Prevention Officer Ramona Magid, and Chief Product Development Officer Dr. Ken Smith have prepared overviews of the proposed grant slates to assist your evaluation of the recommended awards. The overviews 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 overview, all the information considered by each review council is available by clicking on the appropriate link in the Govenda app. This information includes the application, peer reviewer critiques, and the CEO affidavit for each proposal.

The statutory process governing the approval of these grant recommendations 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 are not final until the Oversight Committee approves the awards at the meeting on November 20, 2024. Consistent with the non-disclosure agreement that all Oversight Committee members have signed, please keep the recommendations confidential and do not disclose information to anyone until CPRIT announces the award list publicly at the Oversight Committee meeting. I request that Oversight Committee members not print, email, or save to your computer's hard drive any grant material on the Govenda app. I appreciate your assistance in taking all necessary precautions to protect this information.

These projects recommended for awards are a major step in our efforts to mitigate the effects of cancer in Texas. If you have any questions or would like more information on the review process or any of the proposed projects, CPRIT's staff, including myself, Dr. Le Beau, Ms. Magid, and Dr. Smith are always available. Please feel free to contact us directly should you have any questions.

Thank you for being part of this endeavor.

Sincerely,
Kristen P. Doyle
Chief Executive Officer

ACADEMIC RESEARCH GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of five academic research grant proposals totaling $12,000,000. The recommended grant proposals were submitted in response to the following grant mechanisms: *Recruitment of First-Time, Tenure-Track Faculty Members;* and *Recruitment of Rising Stars*. The Scientific Review Council (SRC) provided a prioritized list of five grant award recommendations to the presiding officers of the PIC and Oversight Committee on October 16, 2024. The PIC approved the awards as presented by the SRC.

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

- Could lead to immediate or long-term medical and scientific breakthroughs in the area of Cancer Prevention or cures for cancer;
- Strengthen and enhance fundamental science in Cancer Research;
- Ensure a comprehensive coordinated approach to Cancer Research and Cancer Prevention;
    - Applies to Recruitment of First-Time, Tenure-Track Faculty Members
- Are interdisciplinary or interinstitutional;
- Address federal or other major research sponsors' priorities in emerging scientific or Technology fields in the area of Cancer Prevention, or cures for cancer;
- Are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- Have a demonstrable economic development benefit to this state;
    - Applies to Recruitment of Rising Stars
- Enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources;
- Expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and
- Address the goals of the Texas Cancer Plan.

Academic Research Award Recommendations Recruitment Cycle 25.1 *RFTFM: Recruitment of First-Time, Tenure-Track Faculty Members* *RRS: Recruitment of Rising Stars*							
Rank	**App. ID**	**Mech.**	**Application Title**	**PI**	**PI organization**	**Budget**	**Final score**
1	RR250017	RFTFM	Targeting Membrane Enzymes by Structure-Based Drug Discovery for Pancreatic Ductal Adenocarcinoma	Fangyu Liu, Ph.D.	The University of Texas Southwestern Medical Center	$2,000,000	1.0
2	RR250052	RFTFM	Harnessing Protein Translation Machinery to Overcome Resistance of KRAS Inhibitors	Xiangdong Lv, Ph.D.	The University of Texas Health Science Center at Houston	$2,000,000	1.0
3	RR250002	RFTFM	Dissecting Niche Cells in Cancer Immunity and Metastasis	Norihiro Goto, M.D., Ph.D.	The University of Texas M.D. Anderson Cancer Center	$2,000,000	1.1
4	RR250014	RFTFM	Decoding the Immune Network Dynamics in Acute Myeloid Leukemia	Xufeng Chen, Ph.D.	The University of Texas M.D. Anderson Cancer Center	$2,000,000	1.1
5	RR250048	RRS	Novel clinical biomarkers and mechanisms of Cardiotoxicity	Daniel Addison, M.D.	The University of Texas Southwestern Medical Center	$4,000,000	1.1

PREVENTION GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of eight prevention grant proposals totaling $13,446,501. The recommended grant proposals were submitted in response to the following grant mechanisms: *Cancer Screening and Early Detection; Dissemination of CPRIT-Funded Cancer Control Interventions;* and *Primary Prevention of Cancer*. The Prevention Review Council (PRC) provided the prioritized list of award recommendations to the presiding officers

of the PIC and Oversight Committee on October 21, 2024. The PIC approved the award recommendations as presented by the PRC.

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

- Ensure a comprehensive coordinated approach to cancer research;
- Are interdisciplinary or interinstitutional;
- 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 side;
- Have a demonstrable economic development benefit to this state; and
- Address the goals of the Texas Cancer Plan

Prevention Award Recommendations
Cycle 25.1
CSD: Cancer Screening and Early Detection
DI: Dissemination of CPRIT-Funded Cancer Control Interventions
PPC: Primary Prevention of Cancer

Rank	App. ID	Mech.	Application Title	PD	Organization	Budget	Final Score
1	PP250006	CSD	Expansion of Cancer Screening and Early Detection Services to Rural & Medically Underserved Communities	Duckworth, Jessica	The Rose	$2,500,000	2.7
2	PP250019	CSD	Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas	Argenbright, Keith	The University of Texas Southwestern Medical Center	$1,499,243	3.1
3	PP250016	PPC	Screening and treatment for unhealthy alcohol use for cancer prevention in Central Texas – 2	Calderon-Mora, Jessica	The University of Texas at Austin	$1,000,000	3.4
4	PP250046	CSD	The Houston Prevenir, Ayudar, Poder (PAP) Project	Zamorano, Abigail	The University of Texas Health	$1,499,997	3.6

Prevention Award Recommendations Cycle 25.1 *CSD: Cancer Screening and Early Detection* *DI: Dissemination of CPRIT-Funded Cancer Control Interventions* *PPC: Primary Prevention of Cancer*							
Rank	**App. ID**	**Mech.**	**Application Title**	**PD**	**Organization**	**Budget**	**Final Score**
					Science Center at Houston		
5	PP250004	CSD	A Virtual, Centralized Lung Cancer Screening Program for Northeast Texas	Minnix, Jennifer	The University of Texas M. D. Anderson Cancer Center	$1,497,342	3.7
6	PP250009	CSD	The Central Texas Colorectal Cancer Screening Program (CTX-CCSP)	Shokar, Navkiran	The University of Texas at Austin	$2,500,000	3.8
7	PP250018	DI	Texas Comprehensive Access & Resources for Early Lung Cancer Prevention (TEX-CARE)	Zoorob, Roger	Baylor College of Medicine	$449,929	3.8
8	PP250005	CSD	Project 80% Colorectal Cancer Screening Program	Foxhall, Lewis	The University of Texas M. D. Anderson Cancer Center	$2,499,990	4.2

PRODUCT DEVELOPMENT RESEARCH GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of nine product development research grant proposals totaling $63,566,375. The recommended grant proposals were submitted in response to the following grant mechanisms: *SEED Awards for Product Development Research; Texas Diagnostic and Devices Company Awards;* and *Texas Therapeutics Company Awards*. The Product Development Review Council (PDRC) provided the prioritized list of award recommendations to the presiding officers on October 29, 2024.

Also on October 29, I notified Oversight Committee members that I granted Dr. Smith a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed

Dr. Smith to negotiate a budget reduction with each company that the PDRC recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

At the PIC meeting on November 6, Dr. Smith presented the nine product development award recommendations with revised budgets. Originally, the cumulative amount of the nine awards equaled $68,863,933; however, Dr. Smith negotiated reduced budgets that led to an overall total of $63,566,375. The PIC approved the awards and funding amounts as recommended by Dr. Smith.

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

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

Product Development Research Recommendations
Cycle 25.1
SEED: SEED Awards for Product Development Research
TDDC: Texas Diagnostic and Devices Company Awards
TTC: Texas Therapeutics Company Awards

Rank	App. ID	Mech.	Application Title	PI	PI organization	Budget	Final score
1	DP250157	TDDC	Clinical Utility Study for the Commercial Launch of Best-in-Class Liver Cancer Screening Blood Test for High-Risk Liver Disease Patients	Patnaik, Ritish	Curve Biosciences	$11,340,000	1.9
2	DP250150	TTC	A Phase 1 Study of Multi-Tymo Associated Antigen Specific T Cells (MT-601) in Patients with Metastatic Pancreatic Cancer following frontline FOLFIRINOX	Vera, Juan F.	Marker Therapeutics, Inc.	$9,513,569	2.1
3	DP250143	SEED	TELOVANCE: A Transient Telomere Lengthening Platform Designed to Enhance the Expansion and Efficacy of Human Cell and Gene Therapies	Sayed, Mohammad E.	Telos Biotechnology	$2,778,945	2.3

Product Development Research Recommendations
Cycle 25.1
SEED: SEED Awards for Product Development Research
TDDC: Texas Diagnostic and Devices Company Awards
TTC: Texas Therapeutics Company Awards

Rank	App. ID	Mech.	Application Title	PI	PI organization	Budget	Final score
4	DP250135	TTC	Personalized Immunotherapy for Recurrent, Resectable Head and Neck Cancer	Pack, Christopher D.	Metaclipse Therapeutics Corporation	$6,080,245	2.4
5	DP250159	TTC	(S)-TASIN-15 Phase 1 Dose Escalation, Optimization & RP2D Determination	Thapar, Neil C.	Barricade Therapeutics, Corp.	$14,005,034	2.4
6	DP250137	SEED	Revolutionizing Solid Tumor Therapy with Bispecific TCRm Antibodies Targeting Intracellular Cancer Targets	Zha, Dongxing	Ypsilon Therapeutics	$2,727,500	2.5
7	DP250140	TTC	A Phase 1 clinical trial of OR-449, a novel oral targeted therapy for pediatric and adult adrenocortical cancer patients	Thacher, Scott M.	Orphagen Pharmaceuticals, Inc.	$10,213,909	2.6
8	DP250142	TTC	Eisbach Bio – Clinical Development of the ALC1 DDR inhibitor EIS-12656	Schomburg, Adrian	Eisback Bio Inc.	$4,750,000	2.7

Product Development Research Recommendations
Cycle 25.1
SEED: SEED Awards for Product Development Research
TDDC: Texas Diagnostic and Devices Company Awards
TTC: Texas Therapeutics Company Awards

Rank	App. ID	Mech.	Application Title	PI	PI organization	Budget	Final score
9	DP250149	SEED	Functional assay of immunoproteasome for patient stratification to checkpoint inhibitor therapy using single-molecule protein sequencing	Swaminathan, Jagannath	Erisyon, INC	$2,157,172	2.8

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE CERTIFICATION – NOVEMBER 2024 AWARDS
DATE:	NOVEMBER 7, 2024

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 Rising Stars
- Recruitment of First-Time Tenure Track Faculty Members
- Texas Therapeutics Company Award
- Texas Device and Diagnostics Company Award
- SEED Awards for Product Development Research
- Cancer Screening and Early Detection
- Primary Prevention of Cancer
- Dissemination of CPRIT-Funded Cancer Control Interventions

The *Recruitment of Established Investigators* and *Texas New Technologies Company Award* mechanisms received applications during this award cycle; however, did not result in recommendations to the Oversight Committee for its November 20, 2024, meeting. 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 awards, 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.

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 CARS are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to CPRIT (through the CPRIT Helpdesk that is managed by GDIT) to allow for a submission after the deadline. The program officer considers any requests for extension and may approve an extension for good cause. When a late filing request is approved, the applicant is notified, and CARS is reopened for a brief period – usually two to three hours – the next business day.

Academic Research:

For recruitment cycles 25.1, one application was received for the Recruitment of Established Investigators RFA, five applications were received for the Recruitment of Rising Stars, and 14 applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA.

All Academic Research RFAs were posted on the Texas.gov eGrants website and all applications were submitted through CARS.

Product Development Research:

For Cycle 25.1, 21 preliminary applications were received for the Texas Therapeutics Company Awards for Product Development Research (TTC) RFA, 13 preliminary applications were received for the Texas Diagnostics and Devices Company Awards for Product Development Research (TDDC) RFA, 13 preliminary applications were received for the Texas New Technologies Company Awards for Product Development Research (TNTC) RFA, and 47 preliminary applications were received for the SEED Awards for Product Development Research (SEED) RFA.

After preliminary review, CPRIT issued invitations to submit full applications to 24 applicants (nine TTC applicants, five TDDC applicants, two TNTC applicants, and eight SEED applicants). Twenty-two applicants submitted full applications.

All Product Development Research RFAs were posted on the Texas.gov eGrants website. All preliminary and full applications were submitted through CARS. Three applicants requested an extension to submit an application after the deadline. The program officer determined that there was good cause for the requests and the deadline was extended. Four preliminary applications were administratively withdrawn.

Prevention:

For prevention cycle 25.1, 16 applications were received for the Cancer Screening and Early Detection RFA, seven applications were received for the Primary Prevention of Cancer RFA, and

one application was received for the Dissemination of CPRIT-Funded Cancer Control Interventions RFA. Three prevention applications were administratively withdrawn.

All prevention RFAs were posted on the Texas.gov eGrants website and 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 (SRC) members for peer review. Product Development Research Award preliminary applications are assigned on a rolling basis to a panel of Product Development Review Council (PDRC) members for peer review. Based upon scores, a subset of applicants is invited to submit full applications during the fiscal year. The PDRC chair and vice chair assign full applications for Product Development Research Awards to peer review panels. All other academic 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:

For cycle 25.1, no applications were withdrawn.

Product Development Research:

For cycle 25.1, no full applications were withdrawn. Four preliminary applications were administratively withdrawn.

Prevention:

For cycle 25.1, five applications were administratively withdrawn.

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 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 25.1

I reviewed and confirmed that the post review conflict of interest statements were signed by the 13 reviewers that attended the Recruitment Review Panel meeting on September 12, 2024.

Product Development Research:

An applicant for a Product Development Research award must first submit a preliminary application, which is reviewed by a rotating panel of up to four PDRC members. Based upon the determination of the preliminary application review panel, an application is invited to submit a full application. The review process ends for those companies that submitted a preliminary application but were not invited to submit a full application. Applicants submitting a full application attend in-person review and are evaluated by a panel of peer reviewers. Applicants recommended after the in-person review must then go through business operations and management due diligence review and intellectual property review. Boyds Consultants, a third-party contractor for CPRIT, conducts the business and operations due diligence review while intellectual property review is conducted by CPRIT's outside counsel. Following due diligence review, the review panel submits its final score and informs the PDRC of its funding recommendation. The PDRC recommends awards 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 preliminary application panel and full application panel as well as the 10 PDRC members that attended the meeting on October 28, 2024, to determine the final slate of recommended awards.

Prevention:

All Prevention applications are reviewed by the peer review panel and then sent to the 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 the 12 peer review members for Prevention Panel 1 (Day 1) on September 10, 2024, the 13 peer review members for Prevention Panel 1 (Day 2) on September 11, 2024, and the three PRC members that attended the Review Council meeting on October 18, 2024.

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.

Academic Research:

The SRC met on September 12, 2024, to consider a total of 14 applications. After review and discussion of these applications, the SRC recommended five applications to the PIC for consideration. Because recruitment applications are assigned to the SRC, programmatic and peer review occur simultaneously when applications are reviewed by the SRC.

Product Development Research:

For cycle 25.1, 22 applications went through full peer review. Of these 22 applications, nine applications were recommended for a due diligence review. Following an evaluation of the business due diligence and IP reports, the review panels recommended nine applications to the PDRC to include in its final slate of proposed awards The PDRC met on October 28, 2024, and after review and discussion recommended all nine applications to the PIC for consideration. The applications were submitted in response to the TTC RFA, the TDDC RFA, and the SEED RFA.

I note that CPRIT CEO Kristen Doyle notified the Oversight Committee on October 29, 2024, that pursuant to T.A.C. § 702.19(e) she granted Dr. Ken Smith, CPRIT's Chief Product Development Officer and PIC member, a waiver from the general prohibition against communicating with a grant applicant while CPRIT is accepting and reviewing applications. The waiver is applicable to communication with the nine companies that were recommended to the PIC during cycle 25.1. The communication waiver allowed Dr. Smith to negotiate reductions in proposed budgets with each company.

Prevention:

Twelve applications were recommended by the peer review panel to the PRC. After review and discussion of these applications, the PRC recommended eight applications to the PIC for consideration.

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 November 6, 2024, 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. No PIC member reported a conflict of interest with any of the grant application recommendations.

The PIC considered 22 applications that were recommended by the Academic Research, Product Development Research, and Prevention Review Councils: five recommendations from the SRC, nine recommendations from the PDRC, and eight recommendations from the PRC. The PIC voted to recommend 22 applications to the Oversight Committee. I note that pursuant to the approved

communication waiver, Dr. Smith negotiated a reduced overall budget with the nine product development grant applicants. At the PIC meeting on November 6, Dr. Smith presented these applications with the negotiated budget. The PIC unanimously recommended the applications to the Oversight Committee with the lower budget amounts.

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

Product Development Research
FY 2025—Cycle 1
SEED Awards for Product Development Research

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA C-25.1-SEED

SEED Awards for Product Development Research

Please also refer to the Instructions for Applicants document

Preliminary Application Deadline: May 1, 2024

Full Application Invitation Issued: July 2024

Full Application Deadline: July 25, 2024

FY 2025

Fiscal Year Award Period

September 1, 2024-August 31, 2025

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RFA VERSION HISTORY

Rev	4/12/2024	RFA release

1. EXECUTIVE SUMMARY

Texas created the Cancer Prevention and Research Institute of Texas (CPRIT) to identify and financially support innovative projects related to the prevention, detection, and treatment of cancer. CPRIT's mission includes investing in Texas-based startup and early-stage oncology companies to narrow the funding gap (sometimes referred to as the "valley of death") between discovery and commercial development.

Texas-based companies and those companies willing to relocate to Texas may submit a preliminary application by the preliminary application deadline, which a panel of experts will review and score for scientific merit and consistency with CPRIT's portfolio, CPRIT will invite the best-scoring companies to submit a full application for review.

A company invited to submit a full application will present the proposed project to a panel of experts. If the panel recommends the company for potential CPRIT investment, the company will undergo due diligence before CPRIT makes a final award decision.

Applicants may request up to $3 million in funding so long as the request is appropriate to the work proposed. Regardless of the amount requested, CPRIT will analyze and negotiate final budgets with grantees in an effort to fund as many worthy projects as possible. CPRIT provides funding via an award contract between CPRIT and the company. The contract includes a negotiated budget tied to agreed goals and objectives (G&Os) and project timeline as well as revenue-sharing terms and regular reporting requirements on the use of CPRIT funds and project progress. CPRIT also requires companies receiving a Product Development Award to contribute the company's own funds toward the project contemporaneously with CPRIT's investment.

Please note that this RFA will use the terms "grant," "award," and "investment" interchangeably to denote the contractual commitment of CPRIT funds to support a company project recommended by an expert review panel and approved by CPRIT's Oversight Committee.

Commitment to Locating in Texas and Maintaining Business Presence in the State

Applying to this RFA indicates that the company will operate in Texas for the foreseeable future should it receive CPRIT funding. Do not apply if this is not your intention.

Texas taxpayer-supported general obligation bonds fund all Product Development Awards. Accordingly, in addition to scientific progress, CPRIT expects every company it funds to appreciably strengthen the Texas life science ecosystem through its presence in the state. A company receiving CPRIT funds must meaningfully commit to locating in Texas and maintaining its business presence within the state.

While CPRIT will work in partnership with your company to advance development of innovative treatments for cancer, we take your obligation to Texas seriously. Fraud, deception, or other actions taken in bad faith to evade the obligation to establish and maintain your status as a Texas company will result in termination, repayment, and any other remedy available by law or contract.

CPRIT developed criteria that CPRIT-funded companies should use to signal the company's commitment to Texas and to developing the state's life science ecosystem. Prior to submitting an application, applicants should familiarize themselves with the criteria specified in section 4.1 "Award Recipients Must Be Texas-Based, For-Profit Companies." If the company receives a CPRIT award, it must attest at least annually to fulfilling CPRIT's Texas location criteria.

2. ABOUT CPRIT

A statewide vote of Texans in 2007 created CPRIT and constitutionally authorized the state to issue $3 billion in taxpayer-backed general obligation bonds to fund cancer prevention and the research and development of innovative methods to prevent, detect, treat, and cure cancer. A second statewide vote in 2019 reauthorized CPRIT and increased the total general obligation bond issuance by another $3 billion, for a total of $6 billion.

2.1. CPRIT's Statutory Mission

The Texas Legislature has charged CPRIT with the following:

- Create and expedite innovation in 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.
- 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.

2.2. CPRIT's Product Development Research Program Priorities

In addition to overarching principles that include scientific excellence, impact on cancer, and increasing the state's life science infrastructure, CPRIT's Oversight Committee establishes annual priorities for each of its 3 programs. The priorities guide CPRIT on the development of RFAs and the evaluation of applications considered for awards.

The Product Development Research Program's priorities for FY25 are as follows:

- Funding novel projects that offer therapeutic or diagnostic benefits; 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 research entities
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level executives
- Providing appropriate return on Texas taxpayer investment

Information about CPRIT's program priorities is available at http://priorities.cprit.texas.gov/.

3. FUNDING INFORMATION AND MATCHING FUNDS REQUIREMENT

3.1. Overview

CPRIT provides project funding via a 3-year contract, with the opportunity to extend the contract duration based upon project progress. Funding is milestone driven, meaning that the company

must fulfill the contractual G&Os associated with one funding tranche before receiving the next disbursement of funds.

3.2. Funding Stage for Texas SEED Company Awards

The SEED Award for Product Development Research supports company formation and preclinical research and development efforts that advance an interesting oncology technology toward a commercially viable business opportunity, ie, make it more attractive to private funding agents.

The ideal SEED Award applicant will be a company with compelling preclinical/discovery stage data around a novel target, compound, device, etc, that warrants further development efforts to establish preclinical proof of concept (POC) on the road to commercialization.

Typically, a SEED Award applicant has completed the following activities:

- Identified a novel therapeutic, diagnostic technology, or clinical tool and shown a biological effect
- Replicated/verified the research in a second model and in a second lab
- Conducted preliminary safety and toxicology testing (in the case of therapeutic agents)
- Shown the product can be manufactured at small scale or as a prototype
- Assessed the business opportunity and organized a business plan that begins to address key issues (clinical utility, target market, financial plan, intellectual property [IP] strategy, technical challenges, etc) and lays out a preliminary development plan (formulation, toxicology, scaleup, IND-enabling studies, phase 1 clinical trials, regulatory pathway, etc)
- Established key preclinical development milestones through IND submission
- Initiated a patent application
- Established a company

SEED Awards provide the funding for the company to begin IND/IDE-enabling studies to support filing the IND/IDE (or equivalent). As an example, in the case of drug candidates, specific technical activities the SEED Award mechanism can fund may include the following:

- Performing target validation
- Conducting lead optimization

- Performing target and cellular potency studies
- Developing and validating biomarker/pharmacodynamic (PD) marker assays
- Determining pharmacokinetic (PK) and exposure parameters; determining whether concentrations that result in significant cell death or tumor growth inhibition in vitro can be safely achieved in vivo; establishing in vivo PD POC
- Evaluating biopharmaceutical properties (absorption/bioavailability, distribution, metabolism, and clearance in rodents and nonrodents)
- Optimizing synthetic/bioengineering route
- Developing a prototype clinical formulation
- Expanding preclinical safety characterization in non-GLP studies
- Expanding in vivo preclinical efficacy characterization in tumor models, including where feasible patient-derived xenograft models, that most closely approximate the initial target indication

SEED Awards may be used to carry out comparable activities for other classes of applications such as medical devices or diagnostics.
Specific business activities the SEED Award mechanism can fund may include the following:

- Competitive analysis
- Extent of unmet need
- Target product profile (TPP)
- Description of development plans including integrated project milestones
- Preparation of clinical development plan
- IP development plans

3.3. Allowable Expenses

Companies may use CPRIT funds for expenses associated only with activities directly related to the specific project that CPRIT is funding. Allowable expenses include the following:

- Salary and fringe benefits
- Research supplies
- Equipment
- Clinical trial expenses
- IP acquisition and protection

- External consultants and service providers
- Travel in support of the project
- Other appropriate research and development costs, subject to certain limitations set forth by Texas law

Texas Health & Safety Code Section 102.203 limits the amount of awarded funds that a company may spend on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

CPRIT's strong preference is to fund research and development rather than construction or facility renovation. Applicants intending to use any CPRIT funds for construction or facility renovation must offer extremely compelling circumstances justifying the request, ie, critical facilities that do not already exist in the state.

3.4. Required Matching Funds

CPRIT requires each company receiving a CPRIT Product Development Research Award to contribute funds under the company's control toward the overall project expenses. The company's expenditure of these "matching funds" must take place at the same time the company is drawing down CPRIT funds; there is no credit toward the matching funds requirement for in-kind expenses or expenditures made prior to the CPRIT award. The amount that the company will contribute toward the project is dependent on the total amount of CPRIT funds committed to the company.

The company must demonstrate that it has available matching funds when CPRIT disburses funds under the contract, not when the company submits the CPRIT application.
See section 9.3 for more information about CPRIT's matching funds requirement.

4. ELIGIBILITY AND RESUBMISSION POLICY

4.1. Award Recipients Must Be Texas-Based, For-Profit Companies

An applicant must be a Texas-based, for-profit company. An applicant may apply prior to company formation, but company formation must take place before award receipt. CPRIT will require the applicant to provide a data universal number system (DUNS) number before award receipt.

CPRIT considers a company to be Texas based if it fulfills at least 4 of the following criteria:

- The US headquarters are physically located in Texas.
- The chief executive officer resides in Texas.
- A majority of the company's personnel, including at least 2 other C-level employees (or equivalent), reside in Texas.
- Manufacturing activities take place in Texas.
- At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
- At least 1 clinical trial site is in Texas.
- The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

If appropriate, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

A company headquartered outside of Texas is eligible to apply for a CPRIT award, but the company must fulfill all location requirements identified in the application within 1 year of receiving the initial disbursement of CPRIT 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.

4.2. Contributors to CPRIT Ineligible to Receive CPRIT Awards

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 one 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.

4.3. Relatives of Oversight Committee Members Ineligible to Receive CPRIT Awards

An applicant is ineligible 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.

4.4. Debarment/Termination of a Federal Grant May Affect Eligibility to Receive CPRIT Awards

The applicant must report whether the company, company representative, or any other individual who contributes to the execution of the proposed project in a substantive, measurable way, regardless of whether the individual receives salary or compensation under the grant award, is ineligible to receive federal grant funds or has had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or any other individual is ineligible to receive federal grant funds or has had a grant terminated for cause, CPRIT will contact the applicant to provide more information to determine eligibility for CPRIT awards.

4.5. Only One Submission Per Applicant

Please note that in any given application round, applicants (a Company or PI) may apply for a single Product Development Award. Applicants should review each RFA and select the program that best fits their development status.

4.6. Resubmission Policy

A preliminary application previously submitted to CPRIT in the FY23 or FY24 review cycles but not recommended for funding may be resubmitted once and must follow all resubmission guidelines. CPRIT will not count against the resubmission limit an application previously submitted in the FY23 or FY24 review cycles if CPRIT administratively withdrew the preliminary or full application without review.

CPRIT considers an application to be a resubmission if the proposed project is substantially 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 the company previously submitted to CPRIT does not constitute a new preliminary application for the purposes of CPRIT's resubmission policy. A change in the type of RFA such as changing from a Texas Therapeutic Company application to a SEED application may constitute a resubmission depending on the number and degree of changes from one application to the other. In such cases, the applicant should contact the program office prior to initiating the subsequent application (see section 10.2). CPRIT does not characterize an application as "submitted" for purposes of the resubmission policy if the applicant or CPRIT administratively withdrew the application prior to review.

5. APPLICATION REVIEW PROCESS AND CRITERIA

5.1. Overview

CPRIT uses a 3-step process to review company projects proposed for funding. The steps include (1) preliminary application, (2) full application and interview, and (3) due diligence review. An integrated panel of individuals with expertise in a wide variety of scientific fields including oncology as well as experts with experience in bringing products to market and those familiar with regulatory approval processes will review the applications. Cancer patient advocates also participate in the review of full applications.

Initially, applicants must submit a preliminary application. Based primarily upon a review of the scientific merit of the project as described in the preliminary application, CPRIT may invite a company to submit a full application and interview. The review of full applications will consider the quality of the research project and management team, commercial viability, product feasibility, scientific merit, project budget, timeline, and goals, the potential suggested by preclinical results, and the opportunity to address unmet medical need. If the review panel is favorably inclined to recommend the full application for funding after the interview, the application will undergo a due diligence review by the panel as well as by third-party reviewers, such as IP counsel. The due diligence review is intended to identify red flags that may negatively impact the panel's final recommendation regarding funding.

CPRIT conducts all stages of the review in confidence to protect the applicant's technological, scientific, and proprietary information. Individuals involved in the review process operate under strict conflict-of-interest prohibitions and nondisclosure agreements. Applicants must not contact or discuss a pending application with anyone involved in making a final decision on the application unless specifically invited by CPRIT to provide information on the proposed project.

CPRIT makes funding decisions via the review process and review criteria described below. CPRIT's Administrative Rules, Chapter 703, Sections 703.6 to 703.8 delineate the review process in more detail.

5.2. Review Process – Preliminary Applications

CPRIT uses a preliminary review process to quickly provide an applicant with feedback about whether the proposed project is compatible with the CPRIT portfolio and mission.

Preliminary applications must be submitted by May 1, 2024, 4 PM central time. A panel of experts will individually review and score the preliminary application using the criteria listed below. The panel reviewers may meet collectively to discuss the final decision regarding the preliminary application and will decide whether to invite the applicant to submit a full application for award consideration. In early July 2024, CPRIT will issue invitations to submit full applications to companies with the best-ranking preliminary application scores. The review process ends after preliminary review for those applicants not invited to submit a full application.

5.3. Review Criteria – Preliminary Applications

The review panel will evaluate the preliminary applications based on the scientific merit of the technology underlying the proposed project and whether the company presents a compelling idea for CPRIT investment.

5.4. Review Process – Full Applications

5.4.1. Product Development and Scientific Review

CPRIT assigns full applications to individual CPRIT product development review panel members for evaluation using the criteria listed in section 5.5. In addition to reviewing the written application, the review panel will provide questions to the company that the company will address during a meeting convened virtually for the applicant to present the application in person and respond to reviewers' questions. To the extent that the company has had any interaction with regulatory agencies, the applicant should provide CPRIT with documents related to that interaction in section 8.8 of the application and also promptly submit any new correspondence that occurs at any time with the agencies during the course of the review.

5.4.2. Due Diligence Review

Following the in-person presentations, a subset of applications that the review panel judges to be most meritorious will move forward for additional in-depth due diligence, including, but not limited to, IP, management team strength, regulatory considerations, manufacturability, and market assessments.

After the due diligence review, the review panel will determine whether to recommend the application for a CPRIT award. The Product Development Review Council will create a final

ranked list of applications recommended for funding by the review panels. The Product Development Review Council's ranking will be based on scores and programmatic priorities.

5.4.3. Program Integration Committee (PIC) Review

The CPRIT Program Integration Committee (PIC) meets to review the Product Development Review Council's final list of applications recommended for funding. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding when creating its comprehensive list of award recommendations for the Oversight Committee. By law, the PIC's list of recommended Product Development Awards may not include any applications not also recommended by the Product Development Review Council.

5.4.4. Oversight Committee Approval

CPRIT's Chief Product Development Officer will present the PIC's award recommendations at a public meeting of the Oversight Committee for approval by two-thirds of the Oversight Committee members present and eligible to vote. By law, the Oversight Committee may not approve any Product Development Awards to applicants not also recommended by the Product Development Review Council and the PIC.

5.5. Review Criteria – Full Application

Generally, the review panel will assess an application on the scientific merit, the quality of the company and management team, the appropriateness of the proposed project, and the potential clinical impact. The criteria provide an overview of topics that may be pertinent to the assessment of SEED Award 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. More specific criteria employed for different product classes are provided in the appendices to this RFA. A successful applicant's proposal will have no significant weaknesses in any of the following areas:

- Significance and impact
- Unmet medical need
- Product validation/POC
- Safety

- Preclinical strength/development to date
- Development plan
- Communications with regulatory agencies
- Anticipated competitive landscape with justification for assumptions of competitive advantages of product in question
- IP
- Business/commercial aspects
- Relevant experience and accomplishments of management team and key consultants
- Production/manufacturing plan
- Overview of clinical/regulatory plan
- Adequate budget and project timeline paired with realistic G&Os
- Overall commitment to Texas

See the appendices for more information on review criteria.

5.6. Confidential, Conflict-Free Review

CPRIT conducts each stage of application review confidentially and requires all CPRIT Product Development Review Panel members, Product Development Review Council members, PIC members, Oversight Committee members, and CPRIT employees with access to grant application information to sign nondisclosure statements regarding the contents of the applications. State law (Texas Health & Safety Code §102.262[b]) protects all technological and scientific information included in the application from public disclosure.

CPRIT will notify an applicant regarding the peer review panel assigned to review the grant application. CPRIT lists the review panel members on our 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.

5.7. Reconsideration of an Application Review Decision Limited to Unreported Conflicts of Interest

CPRIT is committed to providing a fair, unbiased review process conducted by expert reviewers familiar with the science, development stage, and business challenges underlying the project

proposed for funding. That said, application review is a subjective process. **By applying, the applicant agrees and accepts that the sole basis for reconsideration of an application is a reviewer's undisclosed conflict of interest as set forth in CPRIT Administrative Rule 703.9.**

5.8. Prohibited Communication Between Applicant and Reviewers During Review

Except as noted below, CPRIT prohibits communication regarding any aspect of a pending preliminary or full application 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. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

- The communication prohibition begins at the time the applicant submits the preliminary or full application and extends until it receives notice regarding a final decision on the application. An applicant invited to submit a full application who has questions about the application process or the substance of the application should contact the CPRIT Product Development Program Manager.
- The communication prohibition does not apply when CPRIT staff or reviewers specifically invite the applicant to discuss the pending application for purposes of the review process, such as the in-person presentation or to respond to information requests during due diligence review. CPRIT will document communication between the applicant and CPRIT staff/reviewers, including the reason for the communication, as part of the grant review process records.

NOTE: The following individuals are members of the PIC: 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.

6. SUBMISSION GUIDELINES AND DEADLINES

By submitting an application, the applicant accepts the terms and conditions of the RFA. Carefully review information in this section and the *Instructions for Applicants* document to ensure the accurate and complete submission of all components of the application. It is imperative that applicants allow sufficient time to familiarize themselves with the application

format and instructions to avoid unexpected issues. CPRIT will administratively withdraw without review any application that lacks 1 or more required components, exceeds the specified page or word limits, or fails to meet the eligibility requirements listed in section 4.

6.1. Online Application Receipt System

Applicants submit preliminary and full applications via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal are eligible for evaluation.** To create and submit an application, there must be a named Principal Investigator (PI) and a named Application/Authorized Signing Official (ASO) who both have CARS user accounts. NOTE: An application cannot be submitted without ASO approval. The same person may serve as both the PI and the ASO; however, a separate account (with separate username and password) must be set up for each role. The *Instructions for Applicants* document associated with this RFA provides information about establishing a user account.

6.2. Invitations to Submit Full Applications Valid Only for the FY25 Review Process

The invitation to submit a full application is valid only for the current FY25 review cycle. An applicant who is invited to submit a full application for the first FY25 review cycle but does not do so must restart the review process by resubmitting the preliminary application in a future review cycle.

6.3. Preliminary and Full Application Submission Deadlines; Other Key Dates

Preliminary Applications: An applicant may submit a preliminary application via CARS by May 1, 2024, 4 PM central time. Following the review and scoring of all preliminary applications, CPRIT will issue a limited number of invitations to submit a full application in early July 2024 to the companies with the best-ranking scores.

Full Applications: CPRIT will convene panels for review of full applications submitted by the July 25, 2024, deadline. Key dates for the current FY25 review cycle are as follows:

FY25 Review Cycle 1

Full Application Deadline	July 25, 2024; 4 PM central time
In-Person Presentation	September 2024
Due Diligence	September-October 2024
Oversight Committee Meeting	November 20, 2024

6.4. Submission Deadline Extensions

Review cycle schedules are set in advance and do not accommodate receipt of a preliminary or full application days after the deadline. Therefore, potential applicants that are unable to meet the application deadline because of travel, sabbaticals, conferences, prolonged illness, or other leave, etc, should not request additional time to file an application but should instead consider applying in the next review cycle.

In exceptional instances, CPRIT may extend the submission deadline for a preliminary or full application upon a showing of good cause, usually for technology problems related to CARS. In this event, the applicant should submit a request to extend the submission deadline via email to the CPRIT Helpdesk within 8 hours of the submission deadline. If CPRIT approves the applicant's request for extension, then CPRIT will reopen CARS for a 2-hour window to allow an applicant with an unsubmitted application to complete and submit it. CPRIT will document submission deadline extensions, including the reason for the extension, as part of the grant review process records.

CPRIT urges applicants to initiate the registration process in CARS several business days prior to deadline to ensure enough time to complete and apply. The applicant's failure to adequately review application instructions and plan accordingly to avoid unexpected issues is not sufficient grounds to justify approval for a late submission.

6.5. Product Development Review Fee for Full Applications

All applicants submitting a full application must pay a nonrefundable fee of $500 to partially offset the cost of reviewing Product Development Award applications. The application review fee must be postmarked by the full application submission deadline unless CPRIT approves a request to submit the fee after the deadline. Applicants should only submit an application fee after an official invitation to submit a full application has been issued from CPRIT.

Applicants should make the payment by check or money order payable to "Cancer Prevention and Research Institute of Texas." On the check or money order, please indicate the full grant application ID and the name of the applicant (PI) of the application. CPRIT cannot accept electronic or credit card payments.

Applicants using the US Postal Service to mail the application review fee should send it to CPRIT's PO Box (see address below). **DO NOT** use CPRIT's physical address when mailing checks via the US Postal Service.

Cancer Prevention and Research Institute of Texas

PO Box 12097

Austin, TX 78711

Contact name: Michelle Huddleston

Phone 1-512-305-8420

For those applicants using a delivery service (eg, FedEx, UPS) to send the application review fee, CPRIT's physical address is as follows:

Cancer Prevention and Research Institute of Texas

Wm B Travis State Office Building

1701 N Congress Ave Ste 6-127

Austin, TX 78701

Contact name: Michelle Huddleston

Phone 1-512-305-8420

7. PRELIMINARY APPLICATION COMPONENTS

CPRIT strongly advises applicants to attend the webinar offered by CPRIT before applying (https://cprit.texas.gov/news-events/webinars/).

7.1. Abstract (maximum 1,500 characters)

Explain the question or problem to be addressed and the approach to its answer or solution. The aims of the application should 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 an impact on cancer. Describe the unmet medical need addressed by the proposed project. Briefly

explain the product, service, technology, or infrastructure proposed and funding needs. Note that the character limit includes spaces.

7.2. Executive Summary (maximum 2 pages)

The Executive Summary should demonstrate the applicant's ability to think strategically and to orchestrate the execution of key operational aspects of cancer drug, device, or diagnostic development. Listed below are some key elements to address in the Executive Summary. CPRIT encourages applicants to provide concise responses in bulleted format.

a. Company location and year of incorporation
b. Brief description of asset/technology
c. Target/mechanism of action
d. Initial target indication(s)/patient populations: tumor type(s), stage, extent of prior standard-of-care (SOC) therapy
e. Unmet medical need of initial target indications
f. Characteristics of agent/target interaction: potency, reversibility, selectivity, PD effects
g. In vitro preclinical efficacy characterization (eg, cell lines tested with corresponding EC50s selectivity versus normal cells; potency versus competitive agents)
h. In vivo preclinical efficacy characterization (list animal models tested and describe their translational relevance to initial target indication[s]; effectiveness versus SOC; tumor growth inhibition versus tumor regression; effects on survival; combination studies)
i. Preliminary data to support development of devices or diagnostics
j. In vivo tumor PD data supporting in vivo POC
k. Absorption, distribution, metabolism, excretion (ADME), PK, TK (brief statement addressing status of key studies and results if available)
l. Safety characterization to date
m. Biomarker candidates, if any, for companion diagnostic test development
n. Stage of development of the device or diagnostic product
o. Manufacturing/chemistry, manufacturing, and controls (CMC) development status
p. Clinical trial status and plans forward to be covered by the grant

q. Regulatory status and plan (eg, brief summary of agency interactions to date, **including any communications with a regulatory agency, US or foreign**, and planned, likely regulatory paths)
r. High-level overview of work to be done during the funding period, including key milestones and budget estimates by year; manufacturing/CMC; safety toxicology; further in vivo efficacy characterization; biomarker exploration; diagnostic test development; clinical plans
s. Potential competitive advantages together with supporting rationale
t. Senior management team accomplishments in cancer drug development
u. Company financial status/fundraising plans
v. Commitment to Texas

7.3. Slide Presentation (maximum 16 slides)

Provide a slide presentation summarizing the proposed project, scientific support, and management team. The slides should concisely capture all essential elements of the proposed project and should be sufficiently encompassing to be a standalone document. Submit the presentation in PDF format, with 1 slide filling each landscape-orientated page.

7.4. Proposed Project Aims and Budget (maximum 1 page)

Succinctly describe the aims of the proposed project. Provide an anticipated budget request for the project, linking the aims to expected budget amounts. Should CPRIT invite the applicant to submit a full application, the proposed aims and budget will serve as the basis for the project G&Os and requested budget.

7.5. Resubmission Summary (maximum 1 page)

If the applicant submitted a preliminary or full application to CPRIT in previous fiscal years, upload a brief summary of the revised approach, including a summary of the applicant's response to specific feedback. The Resubmission Summary is distinct from the Executive Summary. Clearly indicate to reviewers how the applicant has improved the proposal in response to the critiques from CPRIT. In the Resubmission Summary, refer to specific sections in the resubmission where the reviewer may find further detail on the questions and feedback to the original application.

Responsiveness to previous critiques is a factor in the review. However, reviewers will assess and score the resubmission as a whole, not solely based on improvement and progress made. The review panel for the resubmission may differ from the previous review panel.

8. FULL APPLICATION COMPONENTS

CPRIT does not require or request letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc. Do not submit letters of support as part of your preliminary or full application package. CPRIT will remove any such information from your application before review. Applicants should minimize repetition among application components to the extent possible and use discretion when cross-referencing sections to maximize the amount of information presented within the page limits. Note that where character limits are specified, spaces are included in the character limit.

8.1. Abstract and Significance (maximum 5,000 characters)

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 the unmet medical need addressed by the proposed project and detail 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.

8.2. Layperson's Summary (maximum 1,500 characters)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Explain how the proposed project supports CPRIT's statutory mission. For example, will the project fill a needed gap in patient care or in the development of a sustainable oncology

industry in Texas? Will it synergize with Texas-based resources? Address how the company's work, if successful, may have a major impact on the care of patients with cancer.

Do not include any proprietary information in this section because CPRIT makes the Layperson's Summary publicly available (eg, posted on CPRIT's public website) if the company receives CPRIT funding.

Advocate reviewers use the Layperson's Summary when evaluating the significance and impact of the proposed work.

The Layperson Summary should describe the following:

a. How the proposed project specifically supports CPRIT's mission
b. The overall goals of the work
c. The type(s) of cancer addressed
d. The potential significance of the results
e. The impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer
f. How the company's work, if successful, may have a major impact on the care of patients with cancer

8.3. Goals and Objectives (G&Os) (maximum of 1,200 characters each)

List specific G&Os for each year of the project. G&Os should be clearly delineated, realistic, and consistent with the development plan and timeline to allow for unambiguous measurement of progress. While the G&Os may be more detailed than the proposed project aims included in the applicant's preliminary application, the G&Os should not vary significantly from the proposed project aims.

The G&Os are a fundamental aspect of the application; applicants should carefully consider and justify each proposed G&O. CPRIT will incorporate the G&Os into the award contract and will use the G&Os to evaluate progress of the funded project. Demonstrating the timely and successful achievement of G&Os is necessary before CPRIT will advance the next tranche of funding. While it is laudable to pursue aggressive goals, failure to achieve a goal or objective during the specified time will result in CPRIT withholding funds until the company can show that the company has completed the outstanding issue.

NOTE: CPRIT and the company may negotiate a contractual change to 1 or more G&Os during the funded project as scientific progress and development activities dictate; however, material changes will require substantial justification because the G&Os are part of the foundation of the funding decision by CPRIT.

8.4. Executive Summary (maximum 2 pages)

The Executive Summary should demonstrate the applicant's ability to think strategically and to orchestrate the execution of key operational aspects of cancer drug, device, or diagnostic development. Listed below are some key elements to address in the Executive Summary. CPRIT encourages applicants to provide concise responses in bulleted format. NOTE: The applicant may submit the same Executive Summary it provided in its preliminary application or may update it, as necessary.

a. Company location and year of incorporation
b. Brief description of asset/technology
c. Target/mechanism of action
d. Initial target indication(s)/patient populations: tumor type(s), stage, extent of prior SOC therapy
e. Unmet medical need of initial target indications
f. Characteristics of agent/target interaction: potency, reversibility, selectivity, PD effects
g. In vitro preclinical efficacy characterization (eg, cell lines tested with corresponding EC50s selectivity versus normal cells; potency versus competitive agents)
h. In vivo preclinical efficacy characterization (list animal models tested and describe their translational relevance to initial target indication[s]; effectiveness versus SOC; tumor growth inhibition versus tumor regression; effects on survival; combination studies)
i. Preliminary data to support development of devices or diagnostics
j. In vivo tumor PD data supporting in vivo POC
k. ADME, PK, TK (brief statement addressing status of key studies and results if available)
l. Safety characterization to date
m. Biomarker candidates, if any, for companion diagnostic test development
n. Stage of development of the device or diagnostic product
o. Manufacturing/CMC development status
p. Clinical trial status and plans forward to be covered by the grant

q. Regulatory status and plan (eg, brief summary of agency interactions to date, **including any communications with a regulatory agency, US or foreign**, and planned, likely regulatory paths)
r. High-level overview of work to be done during the funding period, including key milestones and budget estimates by year; manufacturing/CMC; safety toxicology; further in vivo efficacy characterization; biomarker exploration; diagnostic test development; clinical plans
s. Potential competitive advantages together with supporting rationale
t. Senior management team accomplishments in cancer drug development
u. Company financial status/fundraising plans
v. Commitment to Texas

8.5. Timeline (maximum 1 page)

Provide a visual depiction of anticipated major milestones 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. CPRIT will include the timeline in the executed contract. An applicant should avoid including information that it considers confidential or proprietary in this section.

If the development plan (see section 8.8) incorporates or depends on results from parallel studies or development programs that CPRIT is not funding, the Gantt chart/timeline should reference these studies, their timelines, and the contingencies they create or resolve with the studies and G&Os funded by CPRIT.

CPRIT will review timelines for reasonableness. Applicants should provide realistic timelines because the G&Os link directly to the timeline. If CPRIT approves the application for funding, the award contract will include the approved timeline. Adherence to timelines is a criterion for continued support of successful applications.

8.6. Slide Presentation (maximum 10 slides)

Provide a slide presentation summarizing the application. Submit the presentation in PDF format, with 1 slide filling each landscape-orientated page. The slides should succinctly capture all essential elements of the application and should be sufficiently encompassing to be a standalone document.

8.7. Resubmission Summary (maximum 2 pages)

If the applicant submitted a preliminary or full application to CPRIT in previous fiscal years, upload a summary of the revised approach, including a summary of the applicant's response to specific feedback. The Resubmission Summary is distinct from the Executive Summary. Clearly indicate to reviewers how the applicant has improved the proposal in response to the critiques from CPRIT. In the Resubmission Summary, refer to specific sections in the resubmission where the reviewer may find further detail on the questions and feedback to the original application.

Responsiveness to previous critiques is a factor in the review. However, reviewers will assess and score the resubmission as a whole, not solely based on improvement and progress made. The review panel for the resubmission may differ from the previous review panel.

8.8. Development Plan (maximum 12 pages)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that it will address. 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.

The development plan should include a defined product profile (PP). The format for the PP should be a 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 (but not medical device or diagnostic labeling, which must be developed by the applicant in an analogous fashion) 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.

a. 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 or prevention of cancer?
b. 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 PD parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
c. 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.
d. If the company has developed a regulatory plan or has a strategy for interactions with regulatory bodies, provide a summary and a timeline of the planned interactions with regulatory authorities.

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.

If the company has initiated communications with regulatory authorities regarding the product that is the subject of the CPRIT application, copies of any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (eg, FDA, EMA, NMPA, CDSCO) **must be uploaded separately in CARS as a**

standalone document (see IFA section 13.2.10). This is a continuing obligation that extends over the course of the review process. If the applicant receives meeting minutes after submitting the application but before CPRIT has made a final decision on the application, the applicant should contact the CPRIT Helpdesk (see section 10.1) for assistance on filing the additional information.

Applicants developing a cancer therapeutics project should include the following:

Optimization of the lead compound to ensure desired characteristics, including, but not limited to, the following studies:

a. Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced
b. ADME, including, but not limited to, relevant studies based on route of administration
c. Safety (studies as mandated by ICH guidelines)
d. Biomarkers (assays) that potentially target specific patient populations for clinical trials
e. Biomarkers (assays) that can serve as potential PD markers of clinical activity during early clinical trials designed to demonstrate POC
f. 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.

References for the Development Plan section should be provided as a standalone document that will be separately uploaded into CARS. In the interests of brevity include only the most pertinent and current literature. While references will not count toward the Development Plan section page limit, it is essential to be concise and to select only those references relevant to the development plan. Do not use the references to circumvent Development Plan section page limits by including data analysis or other nonbibliographic material.

The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. Please avoid redundancy!

CPRIT recognizes much, if not most, of this information is not available at this stage of development. However, we encourage applicants to be as complete as possible in describing their current stage of development. Applicants developing diagnostics, devices, or cancer-specific services should provide analogous information relevant to their product and project.

8.9. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies must raise substantial funds from other sources to fully fund development. Investors seek financial returns on their investment. An applicant should convince CPRIT that this project has investment return potential based on its risk profile sufficient to raise external capital.

CPRIT review typically focuses on size of market opportunity, development path, and key risk issues. The reviewers will evaluate company applicants based not only on the status of the components of the business plan but also on whether the company acknowledges current weaknesses and gaps and outlines a plan to address them.

The business plan consists of the business rationale overview and summaries of the following key development issues listed below. The Business Plan section may request some of the information that the applicant has included in the development plan. To the extent possible, avoid duplication, redundancy, or references to the development plan in favor of summarizing the information in the business plan.

CPRIT recognizes much of this information is not available at this stage of development. However, we encourage applicants to be as complete as possible in describing their current stage of development.

8.9.1. Business Rationale (maximum 1 page)

Provide a succinct explanation of why this program is an appropriate investment of CPRIT and private funds.

8.9.2. Product and Market (maximum 1 page)

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 SOC, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc. Information on patient populations and market segments is helpful.

8.9.3. Competition and Value Proposition (maximum 1 page)

Provide an overview of the competitive environment (current and future) and how the envisioned product will compete in the marketplace.

8.9.4. Clinical and Regulatory Plans (maximum 1 page)

Provide an overview of plans for 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.

8.9.5. Commercial Strategy (maximum 1 page)

Provide an overview of your anticipated commercial market with a brief assessment of current competition.

8.9.6. Risk Analysis (maximum 1 page)

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.

8.9.7. Funding to Date (This section may exceed 1 page, if necessary)

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. NOTE: This may exceed a 1-page limit if necessary.

8.9.8. Company Financial Overview (maximum 1 page)

Please describe the company's financial condition including cash on hand, runway, burn rate, expenses, debt, working capital and any other metric that would provide insight into the company's finances.

8.9.9. Intellectual Property (IP) (maximum 1 page)

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.

8.9.10. Management Team and Key Personnel (maximum 1 page)

The applicant's management team should be composed of individuals who have the appropriate level of experience in developing and commercializing products.

For each member of the senior management and scientific team, provide a paragraph summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Also indicate the percentage of the person's time devoted to the project. The time indicated by the company is an obligatory commitment, regardless of whether 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.

Provide the same information for other key personnel 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.) NOTE: While the applicant should identify all participants who meet these criteria as "key personnel," CPRIT expects that the applicant will keep to a minimum the number individuals designated as key personnel.

8.10. Biographical Sketches of Key Scientific Personnel (maximum 8 pages)

Provide a biographical sketch for up to 4 key scientific personnel describing their education and training, professional experience, awards and honors, and publications relevant to cancer

research. Each biographical sketch must not exceed 2 pages. CPRIT provides an optional "Product Development Research Programs: Biographical Sketch" template for the applicant's use. The NIH biographical sketch format is also appropriate.

8.11. Commitment to Texas (maximum 1 page)

Describe the company's commitment to locating in Texas and maintaining its business presence in the state. Please identify the criteria specified in section 4.1 "Award Recipients Must Be Texas-Based, For-Profit Companies" that the company will fulfill if it receives a CPRIT award.

8.12. Budget

This is a 3-year funding program, with an opportunity to extend the duration of contract to fully expend awarded funds. The maximum budget award amount the applicant may request is $3 million. All requested funds must be well justified; CPRIT will award financial support based upon the breadth and nature of the project proposed, the transparency of the budget, and the extent to which the company will spend funds in Texas. The total budget included in the full application must not vary significantly from the anticipated budget request included in the applicant's preliminary application. For purposes of this section, "vary significantly" means that the total budget in the full application must not exceed the anticipated budget request in the preliminary application by more than 5%.

The budget must align with the proposed G&Os. CPRIT will disburse funds in tranches tied to the company's achievement of the contractual G&Os.

When preparing the requested budget, applicants should consider the following:

a. Identify the specific equipment that the company proposes to purchase with grant funds. Items that the company includes in the "equipment" budget line should have a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit.
b. Texas Health & Safety Code Section 102.203(d) law limits the amount of grant funds that companies may spend on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). CPRIT's Administrative Rules provide guidance regarding indirect cost recovery.
c. The total amount of CPRIT funds allowed for an individual's FY25 annual salary is $225,000. An individual may request salary proportional to the percent effort up to a maximum of $225,000. Companies may pay salary amounts exceeding this limit from

matching funds. The salary amount does not include fringe benefits. Additionally, CPRIT permits annual salary adjustments of up to a 3% increase for Years 2 and 3, up to the cap of $225,000. CPRIT may revise the FY25 salary cap and future salary caps at its discretion.

The Budget section is composed of 4 subtabs:

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 the company requests funding for a role that the company has not yet filled at the time of submission, the applicant should note "new hire" as name.
b. **Detailed Budget for Year 1:** 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. This section should include only the amount requested from CPRIT. DO NOT include the amount of the matching funds or the budget for the entire proposed period of performance.
c. **Budget for Entire Proposed Period of Performance:** Provide the amount requested from CPRIT for direct costs for all subsequent years. CARS will automatically populate the amounts for *Budget Year 1* based on the information provided in the previous subtabs. This section should include only the amount requested from CPRIT. DO NOT include the amount of the matching funds.
d. **Budget Justification:** The budget should align with the proposed G&Os. 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. This section should include CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds.

9. AWARD CONTRACTS

9.1. Overview

Texas law requires that CPRIT award grant funds via a contract between the company and CPRIT. Contract negotiation commences after the CPRIT Oversight Committee votes to approve

an application for a grant award. Texas law specifies several contract terms that CPRIT must include in the executed agreement, including terms relating to revenue sharing and IP rights, matching funds, and required reporting for fiscal, progress, and compliance.

CPRIT recommends that applicants review CPRIT's Administrative Rules and its related Policies & Procedures Guide (available at www.cprit.texas.gov) for information describing contractual requirements, fiscal and program progress reporting, and limitations on the use of CPRIT grant funds. This RFA highlights information regarding revenue sharing and matching funds below.

9.2. Revenue-Sharing Terms

The contract will include a revenue-sharing agreement. CPRIT publishes its standard revenue-sharing terms on its website at https://cprit.texas.gov/our-programs/product-development-research. CPRIT will include these standard revenue-sharing terms in the award contract unless parties negotiate different revenue-sharing terms that are in the interest of the state and the company.

9.3. Matching Funds

CPRIT requires a company receiving a CPRIT Product Development Research Award to pay a portion of the overall project expenses using money under the company's control. The company's expenditure of these "matching funds" must take place at the same time the company is drawing down CPRIT funds; there is no credit toward the CPRIT matching funds requirement for in-kind expenses or expenditures made prior to the CPRIT award. The company may fulfill its matching funds commitment on a year-by-year basis.

The company demonstrates that it has available matching funds when CPRIT disburses funds pursuant to an executed award contract, not when the company submits the CPRIT application.

CPRIT sets the amount of matching funds the company must contribute toward the project based on the total amount of CPRIT funds committed to the company:

- For companies receiving $20 million or less from CPRIT (inclusive of previous CPRIT awards), the company must dedicate to the project at least $1 of funds under the company's control for every $2 of CPRIT grant award funds.

- A company approved for 1 or more CPRIT product development grants that together total a commitment of more than $20 million must increase their matching fund obligation to at least $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 CPRIT's matching funds policy, the company must dedicate at least $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 1 or more CPRIT product development grants that together total a commitment of more than $30 million must contribute at least $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.

10. CONTACT INFORMATION

10.1. Helpdesk

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration and online submission of applications; Helpdesk staff cannot 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. For "Frequently Asked Technical Questions," please go here.

Hours of operation:	Monday through Friday, 8:00 AM to 6:00 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

10.2. Programmatic Questions

The CPRIT Product Development Program Manager will answer questions regarding CPRIT's Product Development Program Awards and review process, including questions regarding the scientific, product development, and business aspects of applications. For "Frequently Asked Programmatic Questions," please go here.

Tel:	512-305-7676
Email:	proddev@cprit.texas.gov
Website:	www.cprit.texas.gov

11. APPENDIX

11.1. Primary Review Criteria - Therapeutics (Scored)

The following criteria will be used by the Reviewer Panel to assess and score applications. Due to the early-stage nature of SEED projects, CPRIT reviewers are aware that not all criteria listed below will be relevant to a particular SEED application, as some development milestones will remain to be completed.

11.1.1. Unmet Medical Need

a. 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?
b. 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?

11.1.2. Target Validation

a. If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
b. Has engagement of the target with the agent been demonstrated by biochemical assay? What is the potency of the agent?
c. Are there validated downstream 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?
d. Is the target uniquely or substantially overexpressed by tumor versus normal cells?
e. Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
f. Has the company's demonstration of target validation been externally/independently confirmed?
g. 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 therapies?

11.1.3. Preclinical Characterization: Pharmacodynamic (PD) Proof of Concept

a. Considering in vivo preclinical PD 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 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?
b. 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?
c. Have results of preclinical PD studies carried out by the company been externally/independently confirmed?
d. Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
e. How strongly does the preclinical PD profile support the clinical efficacy expectations reflected in the TPP?

11.1.4. Preclinical Characterization: Safety

a. How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
b. Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
c. 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?

11.1.5. Pharmaceutical Properties/Chemistry and Pharmacy

a. 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?
b. 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?
c. Have stability studies been initiated?
d. Is there scope for further lead optimization through structure-activity studies?
e. In the case of biologicals, have efforts to develop a high-quality cell line been initiated? Any data on yields and scalability?
f. Have analytical method development been initiated?
g. Have studies to characterize the (lead) protein begun? Any stability data?

11.1.6. Development Plan/Regulatory Aspects

a. At a high level, are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
b. 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?
c. Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
d. 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?
e. Are development milestones clear and adequately described? Is the overall project timeline realistic?

11.1.7. Competitive Analysis

a. Has the applicant identified likely competitive products on the market and in development?

11.1.8. Intellectual Property (IP)/Freedom to Operate

a. Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
b. Are there opportunities for meaningful patent life extension?
c. Has the applicant secured appropriate licenses conferring freedom to operate?

11.1.9. Chemistry, Manufacturing, and Controls (CMC)

a. How advanced is CMC and manufacturing development?
b. Are there any sourcing issues?
c. Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
d. Do any members of the company have this expertise, or are outside consultants being exclusively relied upon?

11.1.10. Business/Commercial Aspects

a. 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?
b. Does the applicant have a track record of success in raising development funding?

11.1.11. Management Team

a. Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
b. 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?
c. Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

11.2. Secondary Review Criteria (Unscored) Budget and Duration of Support

a. Are the budget and duration of support appropriate for the program of studies described in the application?

b. Is there sufficient clarity in the budget proposal as to how funds will be expended?
c. Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
d. 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?

11.3. Primary Review Criteria for Medical Devices and Diagnostics (Scored)

The following criteria will be used by the Reviewer Panel to assess and score applications. Due to the early-stage nature of SEED projects, CPRIT reviewers are aware that not all criteria listed below will be relevant to a particular SEED application, as some development milestones will remain to be completed.

11.3.1. Unmet Medical Need

a. 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?
b. 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?

11.3.2. Product Validation

a. Technical Validation: Has the product or technology been successfully validated, ie, prototyped, built, and tested in ex vivo, animal, or clinical setting?
b. Have biological proof of principle and product mechanism of action been demonstrated?
c. Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
d. Clinical validation: Are clinical trials required to demonstrate product performance? If so, have they been planned?
e. Biological risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

11.3.3. Production/Manufacturing

a. Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
b. How advanced is manufacturing development?
c. Are there any sourcing issues?

11.3.4. Intellectual Property (IP)/Freedom to Operate

a. Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique knowhow, etc?
b. Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use), and duration of patent life, how strong is the IP?
c. Are there opportunities for meaningful patent life extension?
d. Has applicant secured appropriate licenses conferring freedom to operate, if required?

11.3.5. Market Opportunity

a. Does product address a clearly defined unmet need: lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?
b. Are target indication and market clearly defined?
c. Does the company understand the clinical pathway that leads to utilizing the product?
d. How does product fit with the existing "ecosystem;" ie, are the benefits provided worth the time and cost of implementing the new approach?

11.3.6. Competition

a. Is this a "Whole Product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
b. Has the applicant identified likely competitive products on the market and in development?

11.3.7. Development Plan/Regulatory Aspects

a. At a high level, are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
b. Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

11.3.8. Management Team

a. Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?

b. 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?
c. Has applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

11.3.9. Business/Commercial Aspects

a. Does the applicant need to raise further funds for the CPRIT matching requirement? 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?
b. Has the company anticipated a pricing strategy and reimbursement environment?

11.4. Secondary Review Criteria Budget and Duration of Support (Unscored)

a. Are the budget and duration of support appropriate for the program of studies described in the application?
b. Is there sufficient clarity in the budget proposal as to how funds will be expended?
c. Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
d. 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)
FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6)
Observation Report

Report No.	2024-06-10 PDPRE - 25-1.6
Program Name:	Product Development Research
Panel Name:	FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6)
Panel Date:	June 10, 2024
Report Date:	June 13, 2024

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 FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on June 10, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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: Four (4)
- 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.

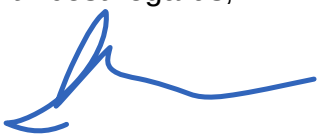
CONCLUSION

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.

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, CRMA, 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)
FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.1
Program Name:	Product Development Research
Panel Name:	FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1) meeting. The meeting was chaired by Kristine Swiderek and conducted via videoconference on June 12, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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 was one (1) Conflict 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, CRMA, 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)
FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.3
Program Name:	Product Development Research
Panel Name:	FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3) meeting. The meeting was chaired by Renzo Canetta and conducted via videoconference on June 12, 2024.

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
- Panelists: One (1) discussion lead and three (3) expert 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 was one (1) 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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.5
Program Name:	Product Development Research
Panel Name:	FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5) meeting. The meeting was chaired by Roy Cosan and conducted via videoconference on June 12, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) application were discussed and seven (7) applications were not discussed
- Panelists: One (1) discussion lead, and three (3) expert 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 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, CRMA, 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)
FYFY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2)
Observation Report

Report No.	2024-06-13 PDPRE-25-1.2
Program Name:	Product Development Research
Panel Name:	FY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2)
Panel Date:	June 13, 2024
Report Date:	June 18, 2024

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 FY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on June 13, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead and three (3) expert 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 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, CRMA, 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)
FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8)
Observation Report

Report No.	2024-06-14 PDPRE-25-1.8
Program Name:	Product Development Research
Panel Name:	FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8)
Panel Date:	June 14, 2024
Report Date:	June 18, 2024

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 FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on June 14, 2024.

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: Three (3) application were discussed and eight (8) applications were not discussed
- Panelists: One (1) discussion lead and three (3) expert 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 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.

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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9)
Observation Report

Report No.	2024-06-18 PDPRE-25-1.9
Program Name:	Product Development Research
Panel Name:	FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9)
Panel Date:	June 18, 2024
Report Date:	June 21, 2024

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 FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on June 18, 2024.

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: Eleven (11) applications were discussed
- Panelists: One (1) discussion lead, and three (3) expert 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 was one (1) Conflict 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7)
Observation Report

Report No.	2024-06-20 PDPRE-25-1.7
Program Name:	Product Development Research
Panel Name:	FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7)
Panel Date:	June 20, 2024
Report Date:	June 21, 2024

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 FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on June 20, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed and eight (8) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-1 (25.1 _PDP-1)
Observation Report

Report No.	2024-09-06 25.1_PDP-1
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-1 (25.1 _PDP-1)
Panel Date:	September 6, 2024
Report Date:	September 9, 2024

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 25.1 Product Development Panel-1 (25.1_PDP-1) meeting. The meeting was chaired by Tian Yu and conducted via videoconference on September 6, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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, CRMA, 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)
25.1 Product Development Panel-2 (25.1_PDP-2)
Observation Report

Report No.	2024-09-09 25.1_PDP-2
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-2 (25.1 _PDP-2)
Panel Date:	September 9, 2024
Report Date:	September 10, 2024

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 25.1 Product Development Panel-2 (25.1_PDP-2) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on September 9, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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: Three (3)
- 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-3 (25.1 _PDP-3)
Observation Report

Report No.	2024-09-09 25.1_PDP-3
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-3 (25.1 _PDP-3)
Panel Date:	September 9, 2024
Report Date:	September 10, 2024

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 25.1 Product Development Panel-3 (25.1_PDP-3) meeting. The meeting was chaired by Renzo Canetta and conducted via videoconference on September 9, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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.

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With best regards,

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

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Product Development Panel-4 (25.1_PDP-4)
Observation Report

Report No.	2024-09-10 25.1_PDP-4
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-4 (25.1 _PDP-4)
Panel Date:	September 10, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-4 (25.1_PDP-4) meeting. The meeting was chaired by Roy Cosan and conducted via videoconference on September 10, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-5 (25.1_PDP-5)
Observation Report

Report No.	2024-09-11 25.1_PDP-5
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-5 (25.1 _PDP-5)
Panel Date:	September 11, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-5 (25.1_PDP-5) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on September 11, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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: Two (2)
- 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, CRMA, 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)
25.1 Product Development Panel-6 (25.1_PDP-6)
Observation Report

Report No.	2024-09-12 25.1_PDP-6
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-6 (25.1 _PDP-6)
Panel Date:	September 12, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-6 (25.1_PDP-6) meeting. The meeting was chaired by David Russler-Germain and conducted via videoconference on September 12, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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, CRMA, 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)
25.1 Product Development Panel-7 (25.1 _PDP-7)
Observation Report

Report No.	2024-09-13 25.1_PDP-7
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-7 (25.1 _PDP-7)
Panel Date:	September 13, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-7 (25.1_PDP-7) meeting. The meeting was chaired by Ginette Serrero and conducted via videoconference on September 13, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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, CRMA, 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)
25.1 Product Development Panel-8 (25.1 _PDP-8)
Observation Report

Report No.	2024-09-13 25.1_PDP-8
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-8 (25.1 _PDP-8)
Panel Date:	September 13, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-8 (25.1_PDP-8) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on September 13, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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, CRMA, 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)
25.1 Product Development Panel-9 (25.1 PDP-9)
Observation Report

Report No.	2024-09-16 25.1_PDP-9
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-9 (25.1 _PDP-9)
Panel Date:	September 16, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-9 (25.1_PDP-9) meeting. The meeting was chaired by Jill Kolesar and conducted via videoconference on September 16, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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 was 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-10 (25.1_PDP-10)
Observation Report

Report No.	2024-09-16 25.1_PDP-10
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-10 (25.1 _PDP-10)
Panel Date:	September 16, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-10 (25.1_PDP-10) meeting. The meeting was chaired by Jun Deng and conducted via videoconference on September 16, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-11 (25.1_PDP-11)
Observation Report

Report No.	2024-09-17 25.1_PDP-11
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-11 (25.1 _PDP-11)
Panel Date:	September 17, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-11 (25.1_PDP-11) meeting. The meeting was chaired by Steven Weinstein and conducted via videoconference on September 17, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-12 (25.1_PDP-12)
Observation Report

Report No.	2024-09-17 25.1_PDP-12
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-12 (25.1 _PDP-12)
Panel Date:	September 17, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-12 (25.1_PDP-12) meeting. The meeting was chaired by Christopher Carpenter and conducted via videoconference on September 17, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-13 (25.1_PDP-13)
Observation Report

Report No.	2024-09-18 25.1_PDP-13
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-13 (25.1 _PDP-13)
Panel Date:	September 18, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-13 (25.1_PDP-13) meeting. The meeting was chaired by William Gmeiner and conducted via videoconference on September 18, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-14 (25.1_PDP-14)
Observation Report

Report No.	2024-09-19 25.1_PDP-14
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-14 (25.1 _PDP-14)
Panel Date:	September 19, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-14 (25.1_PDP-14) meeting. The meeting was chaired by Arnab Ghosh and conducted via videoconference on September 19, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-15 (25.1_PDP-15)
Observation Report

Report No.	2024-09-19 25.1_PDP-15
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-15 (25.1 _PDP-15)
Panel Date:	September 19, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-15 (25.1_PDP-15) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on September 19, 2024.

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) application was discussed
- Panelists: One (1) panel chair, six (6) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-16 (25.1_PDP-16)
Observation Report

Report No.	2024-09-20 25.1_PDP-16
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-16 (25.1 _PDP-16)
Panel Date:	September 20, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-16 (25.1_PDP-16) meeting. The meeting was chaired by Matthew Spear and conducted via videoconference on September 20, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-17 (25.1_PDP-17)
Observation Report

Report No.	2024-09-23 25.1_PDP-17
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-17 (25.1 _PDP-17)
Panel Date:	September 23, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-17 (25.1_PDP-17) meeting. The meeting was chaired by Alan West and conducted via videoconference on September 23, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-18 (25.1_PDP-18)
Observation Report

Report No.	2024-09-24 25.1_PDP-18
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-18 (25.1 _PDP-18)
Panel Date:	September 24, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-18 (25.1_PDP-18) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on September 24, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-19 (25.1_PDP-19)
Observation Report

Report No.	2024-09-25 25.1_PDP-19
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-19 (25.1 _PDP-19)
Panel Date:	September 25, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-19 (25.1_PDP-19) meeting. The meeting was chaired by Kristine Swiderek and conducted via videoconference on September 25, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-20 (25.1_PDP-20)
Observation Report

Report No.	2024-09-26 25.1_PDP-20
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-20 (25.1 _PDP-20)
Panel Date:	September 26, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel-20 (25.1_PDP-20) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on September 26, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: One (1)
- 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, CRMA, 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)
25.1 Product Development Panel - 21 (25.1_PDP - 21)
Observation Report

Report No.	2024-09-26 25.1_PDP - 21
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 21 (25.1 _PDP - 21)
Panel Date:	September 26, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel - 21 (25.1_PDP - 21) meeting. The meeting was chaired by Karen Stein and conducted via videoconference on September 26, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

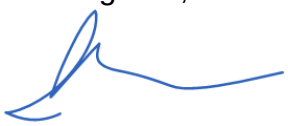
CONCLUSION

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, CRMA, 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)
25.1 Product Development Panel - 22 (25.1_PDP - 22)
Observation Report

Report No.	2024-09-27 25.1_PDP - 22
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 22 (25.1 _PDP - 22)
Panel Date:	September 27, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel - 22 (25.1_PDP - 22) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on September 27, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-7 DD (25.1 PDP-7 DD)
Observation Report

Report No.	2024-10-14 25.1_PDP-7 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-7 DD (25.1 _PDP-7 DD)
Panel Date:	October 14, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-7 DD (25.1_PDP-7 DD) meeting. The meeting was chaired by Ginette Serrero and conducted via videoconference on October 14, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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, CRMA, 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)
25.1 Product Development Panel-9 DD (25.1 PDP-9 DD)
Observation Report

Report No.	2024-10-14 25.1_PDP-9 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-9 DD (25.1 _PDP-9 DD)
Panel Date:	October 14, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-9 DD (25.1_PDP-9 DD) meeting. The meeting was chaired by Jill Kolesar and conducted via videoconference on October 14, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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, CRMA, 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)
25.1 Product Development Panel-5 DD (25.1 PDP-5 DD)
Observation Report

Report No.	2024-10-15 25.1_PDP-5 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-5 DD (25.1 _PDP-5 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-5 DD (25.1_PDP-5 DD) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) and one (1) who remained in the Waiting Room

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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT) 25.1 Product Development Panel-6 DD (25.1 PDP-6 DD) Observation Report

Report No.	2024-10-15 25.1_PDP-6 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-6 DD (25.1 _PDP-6 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-6 DD (25.1_PDP-6 DD) meeting. The meeting was chaired by David Russler-Germain and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, and five (5) expert 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Product Development Panel-8 DD (25.1 PDP-8 DD)
Observation Report

Report No.	2024-10-15 25.1_PDP-8 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-8 DD (25.1 _PDP-8 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-8 DD (25.1_PDP-8 DD) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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, CRMA, 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)
25.1 Product Development Panel-12 DD (25.1 PDP-12 DD)
Observation Report

Report No.	2024-10-16 25.1_PDP-12 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-12 DD (25.1 _PDP-12 DD)
Panel Date:	October 16, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-12 DD (25.1_PDP-12 DD) meeting. The meeting was chaired by Christopher Carpenter and conducted via videoconference on October 16, 2024.

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
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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, CRMA, 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)
25.1 Product Development Panel-2 DD (25.1 _PDP-2 DD)
Observation Report

Report No.	2024-10-17 25.1_PDP-2 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-2 DD (25.1 _PDP-2 DD)
Panel Date:	October 17, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-2 DD (25.1_PDP-2 DD) meeting. The meeting was chaired by Collin Turnbull and conducted via videoconference on October 17, 2024.

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
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: One (1)

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, CRMA, 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)
25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD)
Observation Report

Report No.	2024-10-18 25.1_PDP-20 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD)
Panel Date:	October 18, 2024
Report Date:	October 22, 2024

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 25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on October 18, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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, CRMA, 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) 25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD)Observation Report

Report No.	2024-10-21 2.51_PDP-22 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD)
Panel Date:	October 21, 2024
Report Date:	October 23, 2024

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 25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on October 21, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- Norton Rose Fulbright Law Firm Consultants staff: Three (3) who remained in the Waiting Room

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, CRMA, 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)
25.1 Product Development Review Council Meeting (25.1 PDRC)
Observation Report

Report No.	2024-10-28 25.1 PDRC
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Review Council Meeting (25.1 PDRC)
Panel Date:	October 28, 2024
Report Date:	October 30, 2024

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 25.1 Product Development Review Council Meeting (25.1 PDRC) . The meeting was chaired by Jack Geltosky and conducted via videoconference on October 28, 2024.

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: Nine (9) applications were discussed
- Panelists: One (1) panel chair, one (1) panel vice chair, and eight (8) product development review council memebers
- 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 (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.

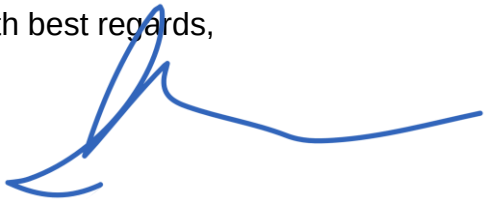
CONCLUSION

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, CRMA, 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 25.1
Awards Announced at the November 20, 2024, Oversight Committee Meeting

The following table 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 25.1 include those received in response to the following Requests for Applications: *SEED Awards for Product Development Research; Texas Diagnostic and Devices Company Awards; Texas Therapeutics Company Awards;* and *Texas New Technology Company 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:			
DP250159	Thapar, Neil C	Barricade Therapeutics, Corp	Rosenfeld, Craig
Applications not considered by the PIC or Oversight Committee:			
DP250115 (preliminary)	Whitney, Duncan	Gregor Diagnostics	Yu, Tian
DP250071 (preliminary)	Li, Yong	SOTLA THERAPEUTICS LLC	Anderson, Karen
DP250075 (preliminary)	Allinson, Bryan	Vanquish Bio	Geltosky, Jack
DP250005 (preliminary)	Carter, Kenneth	Black Canyon Bio, Inc.	Akhavan, David

T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	T.A.C. § 702.19 WAIVER APPROVAL FOR DR. KEN SMITH
DATE:	OCTOBER 29, 2024

Summary

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I have granted Chief Product Development Officer Dr. Ken Smith a waiver from the general prohibition against communicating with a grant applicant while CPRIT is accepting and reviewing applications. The waiver applies to communication with the nine companies that the Product Development Review Council (PDRC) has recommended for grant awards in review cycle 25.1. Approving the waiver promotes CPRIT's objectives and does not give one or more applicants an unfair advantage. No Oversight Committee action related to this waiver is necessary.

Discussion

The Chief Product Development Officer is a statutorily mandated member of the Program Integration Committee (PIC). Texas Administrative Code § 702.19 prohibits substantive communication between the grant applicant and a member of the peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The communication restriction is one way that we prevent even the appearance of unequal treatment in the grant review process. However, the rule provides a process for the CEO to waive the communication restriction in specific circumstances if doing so is in the interest of CPRIT's process and does not give any applicant an unfair advantage.

Approving this waiver allows Dr. Smith to negotiate reductions in proposed budgets with each company prior to Oversight Committee approval. Granting the waiver will not favor any applicant or provide an unfair advantage.

The Oversight Committee does not need to take any action regarding this waiver. Dr. Smith's waiver will be part of the grant record for the FY 2025 product development awards.

High Level Summary of Due Diligence

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Telos Biotechnology for $2,778,945.

No Contingencies

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.

Telos Biotechnology aims to improve CAR T-cell therapy outcomes with TELOVANCE, a telomerase-based treatment that extends telomeres during CAR T-cell manufacturing to delay cell senescence and enhance efficacy. As telomere shortening limits CAR T-cell longevity, TELOVANCE addresses this challenge by selectively extending telomeres in CAR T-cells, improving their therapeutic potential without risk of immortalization.

TELOVANCE's transient telomere extension increases cell survival and cytotoxicity, tackling a key limitation in CAR T-cell therapies, where only 50% of patients achieve long-term remission. This innovation, validated in both in-vitro and in-vivo studies, is positioned to transform CAR T-cell therapy by boosting the performance and durability of the manufactured cells.

The project will transition TELOVANCE production to GMP standards and conduct in-vivo studies for expanded safety testing. Additional studies will explore TELOVANCE's potential in other cell types, expanding its applications beyond hematologic cancers.

CPRIT support will allow Telos to advance TELOVANCE toward commercial readiness and enhance Texas's biotech ecosystem. By establishing a manufacturing presence in Texas, Telos can drive cell therapy innovations and create economic impact through high-value therapeutic developments.

Select Reviewer Comments

"The lack of significant long-term responses in many CAR-T treated patients is a genuine unmet medical need, and Telos is positioned to potentially improve and increase those long-term responses."

"Telovance-treated CAR T-cells showed an increase in persistence six months after injection into mice during pilot safety studies. This is a critically important and clinically relevant result."

"The application proposes the development of an innovative technology that could potentially impact the treatment of cancer and benefit cancer patients greatly. The applicants explain the unique role of Telovance in that it improves the efficacy and durability of cell and gene therapies."

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Ypsilon Therapeutics for $2,727,500.

No Contingencies

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.

Ypsilon Therapeutics is advancing TCR mimic (TCRm) x CD3 antibodies targeting the CT83 peptide, selectively expressed in various solid tumors, to overcome limitations in immune checkpoint inhibitor efficacy. This novel immunotherapy directs T cells to specifically target CT83-expressing tumor cells, enhancing safety and precision.

Leveraging Alloy Therapeutics' TCR discovery platform, Ypsilon has developed TCRm antibodies with high affinity for CT83, engineering them into bispecific CD3 T cell engagers. This approach selectively targets malignant tissues, addressing the unmet need in solid tumor treatment.

This project will develop and validate the TCRm CD3 engagers through bispecific engineering and in-vivo studies in xenograft models, with CPRIT support accelerating preclinical milestones. The project will also facilitate Ypsilon's move to Houston, where they plan to collaborate with MDACC.

CPRIT funding will enable Ypsilon to advance this promising treatment, positioning Texas as a leader in solid tumor immunotherapy and providing new options for patients resistant to existing therapies.

Select Reviewer Comments

"Despite advancements in anti-cancer therapies... the prognosis for patients with solid tumors... continues to be poor. Addressing this need is indeed urgently needed."

"If successful, Ypsilon's bispecific TCRm T cell engager may have a meaningful impact in addressing unmet need. The technologies that result in the first drug could be leveraged to make other engagers that address other HLA and other antigens."

"This proposal, if successful, will result in an innovative product that addresses unmet needs in multiple solid cancers. The upside is significant, and the team is as well-suited to successful execution as any small group could be."

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Erisyon, Inc. for $2,157,172.50

No Contingencies

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.

Erisyon is developing a fluorosequencing-based assay to predict immune checkpoint inhibitor (ICI) resistance in non-small cell lung cancer (NSCLC) patients. By measuring the PSME4 to PSMB10 ratio in immunoproteasomes, this biomarker can identify treatment-resistant tumors, guiding effective therapy selection.

This innovative assay provides absolute molecular quantitation and high sensitivity, enabling accurate antigenicity assessments. With fluorosequencing's capability, Erisyon addresses limitations in current mass spectrometry and antibody assays, enhancing precision in predicting ICI outcomes.

The project will validate the assay's clinical utility through controlled and patient samples, with benchmarking against FDA-approved assays. CPRIT support will enable Erisyon's scale-up and regulatory compliance activities, advancing toward FDA approval.

CPRIT funding will help Erisyon establish a high-impact diagnostic tool in Texas, supporting oncologists with improved patient stratification tools and furthering Texas's contributions to precision cancer diagnostics.

Select Reviewer Comments

"The applicants target a significant challenge in oncology: the early identification of non-small cell lung cancer (NSCLC) patients likely to benefit from checkpoint inhibitor therapy. … a newly developed test, in combination with the success of immune checkpoint inhibitors (ICIs), could benefit a substantial number of cancer patients."

"If successful, the project could significantly expand the eligible patient population for ICI therapy and aid in the development of more effective ICI therapies by offering accurate insights into tumor antigenicity."

"By specifically targeting the PSME4/PSMB10 ratio within tumor cells, this product directly indicates the tumor's status and its potential receptivity to ICI therapy, potentially overcoming a significant barrier in the current approach to cancer treatment."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Marker Therapeutics for $9,513,569.

No Contingencies

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.

Marker Therapeutics is advancing MT-601, a T cell therapy for metastatic pancreatic cancer (mPC), leveraging six tumor-associated antigens (mTAA) highly expressed in pancreatic cancer to reduce tumor escape and off-target effects. MT-601 is designed for outpatient administration, enhancing accessibility while minimizing toxicity, and has shown promising efficacy in lymphoma, with early pancreatic cancer trials indicating robust safety and initial efficacy.

MT-601's unique targeting mechanism allows it to recognize and kill tumor cells through native T cell receptors, addressing a critical need for more effective mPC treatments. Only 52% of patients are eligible for standard mPC chemotherapy due to high toxicity, making MT-601's non-toxic approach particularly valuable. The therapy's design avoids genetic engineering, providing a novel, safer immunotherapy alternative.

Marker's Phase 1 trial will assess MT-601 with FOLFIRINOX in mPC patients across multiple sites, including MD Anderson Cancer Center (MDACC). A dose-escalation phase and dose expansion cohort will evaluate safety and efficacy, with results supporting applications for Regenerative Medicine Advanced Therapy (RMAT) designation and facilitating progression to larger trials.

With CPRIT funding, Marker Therapeutics can advance MT-601 through clinical trials while expanding partnerships with Texas-based entities, supporting Texas's healthcare landscape with cutting-edge mPC treatments. The funding will expedite MT-601's path to market, offering new hope for patients with limited therapeutic options.

Select Reviewer Comments

"Given the unmet medical need of pancreatic cancer, the intended product will significantly address the treatment of this cancer."

"The company has obtained FDA orphan drug designation for MT-601 in treating metastatic pancreatic cancer, and preliminary clinical data show promising safety and efficacy."

"MT-601's target patient population, current clinical stage of development, excellent safety profile, potential for increased efficacy, and lack of genetic engineering gives MT-601 a considerable edge in the market."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Metaclipse Therapeutics for $6,080,245.

No Contingencies

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.

Metaclipse's Membrex vaccine, a personalized autologous immunotherapy, seeks to improve immune responses in head and neck squamous cell carcinoma (HNSCC) by overcoming resistance to immune checkpoint inhibitors (ICIs). Using tumor membrane vesicles (TMVs) from patient tumor tissue, Membrex combines tumor-specific antigens with potent immunostimulatory molecules to induce a more robust T-cell response.

Preclinical studies in HNSCC models have demonstrated Membrex's efficacy, showing increased T-cell infiltration, tumor growth reduction, and metastasis prevention. By sensitizing tumors to anti-PD-1 therapy, Membrex could extend the benefits of ICIs to a broader range of HNSCC patients who currently lack durable responses.

The Phase 1a/b clinical trial will assess Membrex's safety and efficacy in combination with ICIs, conducted at MDACC and additional Texas-based sites. GMP manufacturing will be supported by Texas-based CDMO Fujifilm Diosynth, ensuring operational continuity in the state.

CPRIT funding will enable Metaclipse to advance Membrex in Texas, establishing a base in Houston to drive clinical and operational growth. This support will boost Texas's role in personalized immunotherapy, advancing treatment options for HNSCC patients while fostering economic development.

Select Reviewer Comments

"Membrex vaccine immunotherapy has the potential to significantly address an unmet medical need in the treatment of recurrent HNSCC."

"The successful completion of the goals and objectives of this project will allow go / no-go decisions to be made about further clinical and product development, with strong potential for new drug products that can address current unmet medical needs."

"Membrex is poised to exercise one of many business strategies upon obtaining convincing clinical data in their Phase 2 study."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Barricade Therapeutics, Corp. for $14,005,034.65.

No Contingencies

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.

Barricade Therapeutics is developing TASIN-15, a novel therapy targeting the APC mutation (APCmut) prevalent in colorectal cancer (CRC), which is linked to cancer progression. TASIN-15 selectively inhibits Emopamil binding protein (EBP) with minimal off-target effects, offering a new therapeutic approach for advanced CRC patients.

With an 11% survival rate for metastatic CRC (mCRC), TASIN-15 presents a potential breakthrough by improving efficacy where standard therapies fall short. Preclinical studies show TASIN-15's favorable bioavailability, tissue penetration, and safety, paving the way for Phase 1 trials to establish dosage and efficacy.

Barricade seeks CPRIT funding to complete Phase 1 trials in advanced APCmut CRC patients, establishing TASIN-15's potential as a single-agent and combination therapy. The funding will also support Phase 1b expansion to assess broader therapeutic applications.

With CPRIT support, Barricade will demonstrate Texas's capacity for innovative cancer therapy, positioning TASIN-15 as a leading CRC treatment and strengthening Texas's biotech landscape through advanced clinical development.

Select Reviewer Comments

"Advanced colorectal cancer has a very poor 5-year survival rate. There are few effective, targeted treatments for these patients… A novel, targeted oral treatment would be a welcomed treatment option."

"If TASIN-15 is proven to be safe and effective in CRC, this new therapy would be an important step forward in treating this cancer."

"This therapeutic approach could offer a significant contribution to the management of colorectal cancer."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Orphagen for $10,213,909.

No Contingencies

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.

Orphagen Pharmaceuticals is developing OR-449, a small molecule antagonist targeting steroidogenic factor-1 (SF-1) for treating adrenocortical carcinoma (ACC). SF-1 is highly expressed in ACC and some head and neck and lung squamous carcinomas, with preclinical studies demonstrating OR-449's efficacy in inhibiting tumor growth.

OR-449 is designed to reduce reliance on existing ACC treatments, which have limited success rates. Preclinical toxicology studies have shown no adverse effects, supporting OR-449's advancement into clinical trials for ACC, where options are currently limited.

Orphagen's project aims to complete a Phase 1 clinical trial, exploring dosage and efficacy in adult and pediatric ACC patients. CPRIT funding will support site activation, interim analyses, and manufacturing necessary for the trial's success.

With CPRIT's support, Orphagen will establish its Texas presence, advancing OR-449 as a first-in-class ACC therapy and reinforcing Texas's role in developing rare cancer treatments.

Select Reviewer Comments

"ACC is a rare cancer with severe outcomes in later-stage disease. If this product proves effective, it could provide a significant improvement over the current standard of care for patients with advanced ACC who face limited treatment options."

"OR-449 is a first-in-class inhibitor of SF-1, a novel target for the treatment of ACC... If successful, this drug has the potential to be a breakthrough therapy for both pediatric and adult ACC patients."

"OR-449 has demonstrated considerable preclinical efficacy... The FDA's rare pediatric disease designation for OR-449 and feedback from the pre-IND meeting provide a positive regulatory pathway for advancing this promising candidate."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Eisbach Bio for $4,750,000.

No Contingencies

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.

Eisbach Bio's EIS-12656, a novel DDR helicase inhibitor, targets ALC1 to treat homologous recombination-deficient (HRD) tumors, offering a safer alternative to PARP inhibitors. This innovation addresses a significant need, particularly in PARPi-resistant and HRD-positive tumors with brain metastases.

Preclinical studies show EIS-12656's robust safety profile and blood-brain barrier penetrance, making it suitable for monotherapy and combination therapies with cPARPi and other agents. The drug's efficacy in HRD contexts highlights its transformative potential in solid tumor treatment.

Supported by a partnership with MDACC, Eisbach Bio will conduct Phase I/II trials, with CPRIT funding supporting dose expansion. Relocating to Texas, Eisbach will strengthen Texas's role in oncology, leveraging collaborations to drive EIS-12656's clinical success.

CPRIT funding will support Eisbach's transformative approach to HRD tumor therapy, positioning Texas as a hub for innovative cancer treatments while expanding clinical options for HRD patients.

Select Reviewer Comments

"EIS-12656 has the potential to be a game-changing therapy for patients suffering from HRD solid tumors... with significant potential to improve outcomes for those who have developed resistance to PARP inhibitors."

"As a first-in-class allosteric inhibitor of ALC1, EIS-12656 represents a novel approach, targeting HRD tumors with potential broad applicability across multiple cancer types."

"EIS-12656 demonstrated a markedly superior toxicity profile in comparison with currently available therapies targeting DDR pathways, and the FDA's clearance of the IND underscores the strength of the preclinical data."

TDDC

Curve assay against a gold standard (MRI), with results showing 95% sensitivity and 96% specificity."

"The market opportunity here appears strong, with a projected market size of over $10B in the U.S. for surveilling high-risk liver disease patients. Interviews with target physicians indicate that 92% are willing to order this new test if it can be reimbursed."

De-Identified Overall Evaluation Scores

SEED Awards for Product Development Research

Product Development Research Cycle 25.1

Full Application Review

Application ID	Final Overall Evaluation Score
DP250143*	2.3
DP250137*	2.5
DP250149*	2.8
L	3.6
M	4.1
N	4.4

* Recommended for funding.

SEED Awards for Product Development Research

Product Development Research Cycle 25.1

Final Scores for Preliminary Application Review

CPRIT uses a preliminary application review process to quickly provide an applicant with feedback about whether the proposed project is compatible with the CPRIT portfolio and mission. A panel of experts individually reviewed and scored preliminary applications using the criteria listed in the Request for Applications (RFA). These are the final overall evaluation scores for preliminary applications that were not invited to submit full applications. The review process ends after preliminary review for those applicants not invited to submit a full application.

Application ID	Final Overall Score
Ca	2.0
Cb	2.2
Cc	2.3
Cd	2.3
Ce	2.5
Cf	2.5
Cg	2.5
Ch	2.6
Ci	2.6
Cj	2.8
Ck	2.8
Cl	2.8
Cm	2.8
Cn	2.8
Co	2.8
Cp	2.8
Cq	3.0
Cr	3.0
Cs	3.0
Ct	3.0
Cu	3.0
Cv	3.3
Cw	3.3
Cx	3.3
Cy	3.3
Cz	3.4
Da	3.4
Db	3.5
Dc	3.5

Application ID	Final Overall Score
Dd	3.6
De	3.7
Df	3.8
Dg	3.8
Dh	3.8
Di	4.0
Dj	4.0

Final Overall Evaluation Scores and Rank Order Scores

October 29, 2024

Dr. David Cummings
CPRIT Oversight Committee Chair
Via email to dcummingsmd@yahoo.com

Ms. Kristen Pauling Doyle
CPRIT Program Integration Committee Chair
Via email to kdoyle@cprit.texas.gov

Dr. Cummings and Ms. Doyle,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 25.1 grant award cycle. The PDRC convened on October 28, 2024, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Curve Biosciences, Marker Therapeutics, Inc., Telos Biotechnology, Metaclipse Therapeutics Corp., Barricade Therapeutics, Corp., Ypsilon Therapeutics, Orphagen Pharmaceuticals, Inc., Eisbach Bio Inc., and Erisyon Inc. The attached table reflects the ranked award recommendation for the nine (9) grant applications. The recommendations contain no contingency.

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

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Council

CPRIT 25.1 Product Development Research
Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Application Title	Organization	Final Overall Score	Recommended Budget
1	DP250157	TDDC	New	Patnaik, R	Clinical Utility Study for the Commercial Launch of a Best-in-Class Liver Cancer Screening Blood Test for High-Risk Liver Disease Patients	Curve Biosciences	1.9	$ 12,600,000
2	DP250150	TTC	New	Vera, J	A Phase 1 Study of Multi-Tumor Associated Antigen Specific T Cells (MT-601) in Patients with Metastatic Pancreatic Cancer following frontline FOLFIRINOX	Marker Therapeutics, Inc.	2.1	$ 10,226,179
3	DP250143	SEED	Resubmission	Sayed, M	TELOVANCE: A Transient Telomere Lengthening Platform Designed to Enhance the Expansion and Efficacy of Human Cell and Gene Therapies	Telos Biotechnology	2.3	$ 2,998,945
4	DP250135	TTC	Resubmission	Pack, C	Personalized Immunotherapy for Recurrent, Resectable Head and Neck Cancer	Metaclipse Therapeutics Corporation	2.4	$ 6,395,245
5	DP250159	TTC	New	Thapar, N	(S)-TASIN-15 Phase 1 Dose Escalation, Optimization & RP2D Determination	Barricade Therapeutics, Corp.	2.4	$ 15,485,443
6	DP250137	SEED	New	Zha, D	Revolutionizing Solid Tumor Therapy with Bispecific TCRm Antibodies Targeting Intracellular Cancer Targets	Ypsilon Therapeutics	2.5	$ 2,997,500
7	DP250140	TTC	New	Thacher, S	A Phase 1 clinical trial of OR-449, a novel oral targeted therapy for pediatric and adult adrenocortical cancer patients	Orphagen Pharmaceuticals, Inc.	2.6	$ 10,917,769
8	DP250142	TTC	Resubmission	Schomburg, A	Eisbach Bio - Clinical Development of the ALC1 DDR inhibitor EIS-12656	Eisbach Bio Inc.	2.7	$ 5,000,000
9	DP250149	SEED	New	Swaminathan, J	Functional assay of immunoproteasome for patient stratification to checkpoint inhibitor therapy using single-molecule protein sequencing	Erisyon, INC	2.8	$ 2,242,852

Cancer Prevention & Research
Institute of Texas

CEO Affidavit
Supporting Information

Product Development Research
FY 2025—Cycle 1
Texas Diagnostic and Devices
Company Awards

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA C-25.1-TDDC

Texas Diagnostic and Devices Company Awards for Product Development Research

Please also refer to the Instructions for Applicants document

Preliminary Application Deadline: May 1, 2024

Full Application Invitation Issued: July 2024

Full Application Deadline: July 25, 2024

FY 2025

Fiscal Year Award Period

September 1, 2024-August 31, 2025

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev	4/12/2024	RFA release

1. EXECUTIVE SUMMARY

Texas created the Cancer Prevention and Research Institute of Texas (CPRIT) to identify and financially support innovative projects related to the prevention, detection, and treatment of cancer. CPRIT's mission includes investing in Texas-based startup and early-stage oncology companies to narrow the funding gap (sometimes referred to as the "valley of death") between discovery and commercial development.

Texas-based companies and those companies willing to relocate to Texas may submit a preliminary application by the preliminary application deadline, which a panel of experts will review and score for scientific merit and consistency with CPRIT's portfolio. CPRIT will invite the best-scoring companies to submit a full application for review.

A company invited to submit a full application will present the proposed project to a panel of experts. If the panel recommends the company for potential CPRIT investment, the company will undergo due diligence before CPRIT makes a final award decision.

Applicants may request any amount of funding appropriate to the work proposed. Applicants should be cognizant, however, that CPRIT has limited funds for company investment (approximately $70 million per fiscal year). CPRIT will consider whether a project requesting a significant amount of funding is of such demonstrable importance in terms of innovation and impact that it should displace other worthy investments. Regardless of the amount requested, CPRIT will analyze and negotiate final budgets with grantees in an effort to fund as many worthy projects as possible.

CPRIT provides funding via an award contract between CPRIT and the company. The contract includes a negotiated budget tied to agreed goals and objectives (G&Os) and project timeline as well as revenue-sharing terms and regular reporting requirements on the use of CPRIT funds and project progress. CPRIT also requires companies receiving a Product Development Award to contribute the company's own funds toward the project contemporaneously with CPRIT's investment.

Commitment to Locating in Texas and Maintaining Business Presence in the State

Applying to this RFA indicates that the company will operate in Texas for the foreseeable future should it receive CPRIT funding. Do not apply if this is not your intention.

Texas taxpayer-supported general obligation bonds fund all Product Development Awards. Accordingly, in addition to scientific progress, CPRIT expects every company it funds to appreciably strengthen the Texas life science ecosystem through its presence in the state. A company receiving CPRIT funds must meaningfully commit to locating in Texas and maintaining its business presence within the state.

While CPRIT will work in partnership with your company to advance development of innovative treatments for cancer, we take your obligation to Texas seriously. Fraud, deception, or other actions taken in bad faith to evade the obligation to establish and maintain your status as a Texas company will result in termination, repayment, and any other remedy available by law or contract.

CPRIT developed criteria that CPRIT-funded companies must use to signal the company's commitment to Texas and to developing the state's life science ecosystem. Prior to submitting an application, applicants should familiarize themselves with the criteria specified in section 4.1 "Award Recipients Must Be Texas-Based, For-Profit Companies." If the company receives a CPRIT award, it must attest at least annually to fulfilling CPRIT's Texas location criteria.

Please note that this RFA will use the terms "grant," "award," and "investment" interchangeably to denote the contractual commitment of CPRIT funds to support a company project recommended by an expert review panel and approved by CPRIT's Oversight Committee.

2. ABOUT CPRIT

A statewide vote of Texans in 2007 created CPRIT and constitutionally authorized the state to issue $3 billion in taxpayer-backed general obligation bonds to fund cancer prevention and the research and development of innovative methods to prevent, detect, treat, and cure cancer. A second statewide vote in 2019 reauthorized CPRIT and increased the total general obligation bond issuance by another $3 billion, for a total of $6 billion.

2.1. CPRIT's Statutory Mission

The Texas Legislature has charged CPRIT with the following:

- Create and expedite innovation in 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.
- 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.

2.2. CPRIT's Product Development Research Program Priorities

In addition to overarching principles that include scientific excellence, impact on cancer, and increasing the state's life science infrastructure, CPRIT's Oversight Committee establishes annual priorities for each of its 3 programs. The priorities guide CPRIT in the development of RFAs and the evaluation of applications considered for awards.

The Product Development Research Program's priorities for FY 2025 are as follows:

- Funding novel projects that offer therapeutic or diagnostic benefits; 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 research entities
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level executives
- Providing appropriate return on Texas taxpayer investment

Information about CPRIT's program priorities is available at http://priorities.cprit.texas.gov/.

3. FUNDING INFORMATION AND MATCHING FUNDS REQUIREMENT

3.1. Overview

CPRIT provides project funding via a 3-year contract, with the opportunity to extend the contract duration based upon project progress. Funding is milestone driven, meaning that the company must fulfill the contractual G&Os associated with 1 funding tranche before receiving the next disbursement of funds.

3.2. Funding Stage for Texas Diagnostic and Device Company Awards

Funding available through this RFA supports the ongoing research and development of diagnostic tests and devices to treat, detect, diagnose, monitor, and assist in the treatment of cancer. Relevant areas include the following:

- Devices and assays for cancer detection, diagnosis, prognosis, monitoring, treatment, and prediction of response or resistance to treatment
- Markers for cancer prevention and control; companion diagnostic to a therapy
- Development of diagnostic tests to distinguish high-risk early lesions

Generally, at the time that an applicant applies to CPRIT pursuant to this RFA, the company has developed a commercial prototype of the device or a pictorial representation of the functional components/elements of the device. With respect to diagnostics, the company has developed assays that work on human samples and whose importance is well justified for development into clinical assays. The applicant should be working toward submitting an Investigational Device Exemption (IDE) or a 501(k) or Premarketing Approval (PMA) and is typically within 1 year from filing an IDE (or later stage work). Potential applicants that are not at or near this stage of product development should consider applying for a Texas Seed Company Award.

With appropriate justification, companies may use CPRIT funds to support continuing proof-of-concept studies, product validation, design, production, manufacturing and development, and clinical studies demonstrating safety and efficacy.

CPRIT typically does not fund efforts outside of these parameters. Companies that have clinically demonstrated safety and efficacy should be able to acquire necessary capital via other sources; any request for later clinical trials must explicitly justify why CPRIT funding is

appropriate. However, by exception, CPRIT may consider later-stage clinical trials and other development activities where exceptional circumstances warrant investment.

3.3. Allowable Expenses

Companies may use CPRIT funds for expenses associated only with activities directly related to the specific project that CPRIT is funding. Allowable expenses include the following:

- 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
- Other appropriate research and development costs, subject to certain limitations set forth by Texas law

Texas Health and Safety Code Section 102.203 limits the amount of awarded funds that a company may spend on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

CPRIT's strong preference is to fund research and development rather than construction or facility renovation. Applicants intending to use any CPRIT funds for construction or facility renovation must offer extremely compelling circumstances justifying the request, ie, critical facilities that do not already exist in the state.

3.4. Required Matching Funds

CPRIT requires each company receiving a CPRIT Product Development Research Award to contribute funds under the company's control toward the overall project expenses. The company's expenditure of these "matching funds" must take place at the same time the company is drawing down CPRIT funds; there is no credit toward the matching funds requirement for in-kind expenses or expenditures made prior to the CPRIT award. The amount that the company will contribute toward the project is dependent on the total amount of CPRIT funds committed to the company.

The company must demonstrate that it has available matching funds when CPRIT disburses funds under the contract, not when the company submits the CPRIT application.

See section 9.3 for more information about CPRIT's matching funds requirement.

4. ELIGIBILITY AND RESUBMISSION POLICY

4.1. Award Recipients Must Be Texas-Based, For-Profit Companies

An applicant must be a Texas-based, for-profit company. An applicant may apply prior to company formation, but company formation must take place before award receipt. CPRIT will require the applicant to provide a data universal number system (DUNS) number before award receipt.

CPRIT considers a company to be Texas based if it fulfills at least 4 of the following criteria:

- The US headquarters are physically located in Texas.
- The chief executive officer resides in Texas.
- A majority of the company's personnel, including at least 2 other C-level employees (or equivalent), reside in Texas.
- Manufacturing activities take place in Texas.
- At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
- At least 1 clinical trial site is in Texas.
- The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

If appropriate, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

A company headquartered outside of Texas is eligible to apply for a CPRIT award, but the company must fulfill all location requirements identified in the application within 1 year of receiving the initial disbursement of CPRIT 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.

4.2. Contributors to CPRIT Ineligible to Receive CPRIT Awards

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 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.

4.3. Relatives of Oversight Committee Members Ineligible to Receive CPRIT Awards

An applicant is ineligible 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.

4.4. Debarment/Termination of a Federal Grant May Affect Eligibility to Receive CPRIT Awards

The applicant must report whether the company, company representative, or any other individual who contributes to the execution of the proposed project in a substantive, measurable way, regardless of whether the individual receives salary or compensation under the grant award, is ineligible to receive federal grant funds or has had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or any other individual is ineligible to receive federal grant funds or has had a grant terminated for cause, CPRIT will contact the applicant to provide more information to determine eligibility for CPRIT awards.

4.5. Only One Submission Per Applicant

Please note that in any given application round, applicants (a Company or PI) may apply for a single Product Development Award. Applicants should review each RFA and select the program that best fits their development status.

4.6. Resubmission Policy

A preliminary application previously submitted to CPRIT in fiscal year 2023 (FY23) or FY24 review cycles, but not recommended for funding, may be resubmitted once and must follow all resubmission guidelines. CPRIT will not count against the resubmission limit an application

previously submitted in the FY23 or FY24 review cycles if CPRIT administratively withdrew the preliminary or full application without review.

CPRIT considers an application to be a resubmission if the proposed project is substantially 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 the company previously submitted to CPRIT does not constitute a new preliminary application for the purposes of CPRIT's resubmission policy. A change in the type of RFA, such as changing from a Texas Diagnostic and Device Company application to a Seed application, may constitute a resubmission depending on the number and degree of changes from one application to the other. In such cases, the applicant should contact the program office prior to initiating the subsequent application (see section 10.2). CPRIT does not characterize an application as "submitted" for purposes of the resubmission policy if the applicant or CPRIT administratively withdrew the application prior to review.

5. APPLICATION REVIEW PROCESS AND CRITERIA

5.1. Overview

CPRIT uses a 3-step process to review company projects proposed for funding. The steps include (1) preliminary application, (2) full application and interview, and (3) due diligence review. An integrated panel of individuals with expertise in a wide variety of scientific fields including oncology as well as experts with experience in bringing products to market and those familiar with regulatory approval processes will review the applications. Cancer patient advocates also participate in the review of full applications.

Initially, applicants must submit a preliminary application. Based primarily upon a review of the scientific merit of the project as described in the preliminary application, CPRIT may invite a company to submit a full application and interview. The review of full applications will consider the quality of the research project and management team, commercial viability, product feasibility, scientific merit, project budget, timeline and goals, the potential suggested by preclinical results, and the opportunity to address unmet medical need. If the review panel is favorably inclined to recommend the full application for funding after the interview, the application will undergo a due diligence review by the panel as well as by third-party reviewers,

such as IP counsel. The due diligence review is intended to identify red flags that may negatively impact the panel's final recommendation regarding funding.

CPRIT conducts all stages of the review in confidence to protect the applicant's technological, scientific, and proprietary information. Individuals involved in the review process operate under strict conflict-of-interest prohibitions and nondisclosure agreements. Applicants must not contact or discuss a pending application with anyone involved in making a final decision on the application unless specifically invited by CPRIT to provide information on the proposed project.

CPRIT makes funding decisions via the review process and review criteria described below. CPRIT's Administrative Rules, Chapter 703, Sections 703.6 to 703.8 delineate the review process in more detail.

5.2. Review Process – Preliminary Applications

CPRIT uses a preliminary review process to quickly provide an applicant with feedback about whether the proposed project is compatible with the CPRIT portfolio and mission.

Preliminary applications must be submitted by May 1, 2024, 4 PM central time. A panel of experts will individually review and score the preliminary application using the criteria listed below. The panel reviewers may meet collectively to discuss the final decision regarding the preliminary application and will decide whether to invite the applicant to submit a full application for award consideration. In early July 2024, CPRIT will issue invitations to submit full applications to companies with the best-ranking preliminary application scores. The review process ends after preliminary review for those applicants not invited to submit a full application.

5.3. Review Criteria – Preliminary Applications

The review panel will evaluate the preliminary applications based on the scientific merit of the technology underlying the proposed project and whether the company presents a compelling idea for CPRIT investment.

5.4. Review Process – Full Applications

5.4.1. Product Development and Scientific Review

CPRIT assigns full applications to individual CPRIT product development review panel members for evaluation using the criteria listed in section 5.5. In addition to reviewing the written application, the review panel will provide questions to the company that the company

will address during a meeting convened virtually for the applicant to present the application in person. Importantly, the applicant should provide CPRIT with any correspondence that the company has conducted with regulatory agencies (eg, the FDA) in section 8.8.6 of the application and also promptly submit any new correspondence that occurs at any time during the course of the review.

5.4.2. Due Diligence Review

Following the in-person presentations, a subset of applications that the review panel judges to be most meritorious will move forward for additional in-depth due diligence, including, but not limited to, IP, management team strength, regulatory considerations, manufacturability, and market assessments.

After the due diligence review, the review panel will determine whether to recommend the application for a CPRIT award. The Product Development Review Council will create a final ranked list of applications recommended by the review panels for funding. The Product Development Review Council's ranking will be based on scores and programmatic priorities.

5.4.3. Program Integration Committee (PIC) Review

The CPRIT Program Integration Committee (PIC) meets to review the Product Development Review Council's final list of applications recommended for funding. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding when creating its comprehensive list of award recommendations for the Oversight Committee. By law, the PIC's list of recommended Product Development Awards may not include any applications not also recommended by the Product Development Review Council.

5.4.4. Oversight Committee Approval

CPRIT's Chief Product Development Officer will present the PIC's award recommendations at a public meeting of the Oversight Committee for approval by two-thirds of the Oversight Committee members present and eligible to vote. By law, the Oversight Committee may not approve any Product Development Awards to applicants not also recommended by the Product Development Review Council and the PIC.

5.5. Review Criteria – Full Application

Generally, the review panel will assess an application on the scientific merit, the quality of the company and management team, the appropriateness of the proposed project, and the potential clinical impact. A successful applicant's proposal will have no significant weaknesses in any of the following areas:

- Unmet medical need
- Potential clinical impact
- Relevant proof-of-concept studies (including preclinical safety/efficacy studies) and, where relevant, target validity studies supporting expectations of clinical impact
- Proposed integrated product development plan (IPDP)
- Communications with regulatory agencies
- Present and anticipated competitive landscape, together with justification for assumptions of competitive advantages of product in question
- IP
- Business/commercialization prospects
- Relevant experience and accomplishments of management team and key consultants
- Adequate budget and project timeline paired with realistic G&Os
- Overall commitment to Texas

See the appendix for more information on review criteria.

5.6. Confidential, Conflict-Free Review

CPRIT conducts each stage of application review confidentially and requires all CPRIT Product Development Review Panel members, Product Development Review Council members, PIC members, Oversight Committee members, and CPRIT employees with access to grant application information to sign nondisclosure statements regarding the contents of the applications. State law (Texas Health & Safety Code §102.262[b]) protects all technological and scientific information included in the application from public disclosure.

CPRIT will notify an applicant regarding the peer review panel assigned to review the grant application. CPRIT lists the review panel members on our 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.

5.7. Reconsideration of an Application Review Decision Limited to Unreported Conflicts of Interest

CPRIT is committed to providing a fair, unbiased review process conducted by expert reviewers familiar with the science, development stage, and business challenges underlying the project proposed for funding. That said, application review is a subjective process. **By applying, the applicant agrees and accepts that the sole basis for reconsideration of an application is a reviewer's undisclosed conflict of interest as set forth in CPRIT Administrative Rule 703.9.**

5.8. Prohibited Communication Between Applicant and Reviewers During Review

Except as noted below, CPRIT prohibits communication regarding any aspect of a pending preliminary or full application 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. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

- The communication prohibition begins at the time the applicant submits the preliminary or full application and extends until it receives notice regarding a final decision on the application. An applicant invited to submit a full application who has questions about the application process or the substance of the full application should contact the CPRIT Product Development Program Manager.
- The communication prohibition does not apply when CPRIT staff or reviewers specifically invite the applicant to discuss the pending application for purposes of the review process, such as the in-person presentation or to respond to information requests during due diligence review. CPRIT will document communication between the applicant and CPRIT staff/reviewers, including the reason for the communication, as part of the grant review process records.

NOTE: The following individuals are members of the PIC: 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.

6. SUBMISSION GUIDELINES AND DEADLINES

By submitting an application, the applicant accepts the terms and conditions of the RFA.

Carefully review information in this section and the *Instructions for Applicants* document to ensure the accurate and complete submission of all components of the application. It is imperative that applicants allow sufficient time to familiarize themselves with the application format and instructions to avoid unexpected issues. CPRIT will administratively withdraw without review any application that lacks 1 or more required components, exceeds the specified page or word limits, or fails to meet the eligibility requirements listed in section 4.

6.1. Online Application Receipt System

Applicants submit preliminary and full applications via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal are eligible for evaluation.** To create and submit an application, there must be a named Principal Investigator (PI) and a named Application/Authorized Signing Official (ASO) who both have CARS user accounts. NOTE: An application cannot be submitted without ASO approval. The same person may serve as both the PI and the ASO; however, a separate account (with separate username and password) must be set up for each role. The *Instructions for Applicants* document associated with this RFA provides information about establishing a user account.

6.2. Invitations to Submit Full Applications Valid Only for the FY25 Review Process

The invitation to submit a full application is valid only for the current FY25 review cycle. An applicant who is invited to submit a full application for the first FY25 review cycle but does not do so must restart the review process by resubmitting the preliminary application in a future review cycle.

6.3. Preliminary and Full Application Submission Deadlines; Other Key Dates

Preliminary Applications: An applicant may submit a preliminary application via CARS by May 1, 2024, 4 PM central time. Following the review and scoring of all preliminary applications, CPRIT will issue a limited number of invitations to submit a full application in early July 2024 to the companies with the best-ranking scores.

Full Applications: CPRIT will convene panels for review of full applications submitted by the July 25, 2024, deadline. Key dates for the current FY25 review cycle are as follows:

FY25 Review Cycle 1

Full Application Deadline	July 25, 2024; 4 PM central time
In-Person Presentation	September 2024
Due Diligence	September-October 2024
Oversight Committee Meeting	November 20, 2024

6.4. Submission Deadline Extensions

Review cycle schedules are set in advance and do not accommodate receipt of a preliminary or full application days after the deadline. Therefore, potential applicants that are unable to meet the application deadline because of travel, sabbaticals, conferences, prolonged illness, or other leave, etc, should not request additional time to file the application but should instead consider applying in the next review cycle.

In exceptional instances CPRIT may extend the submission deadline for a preliminary or full application upon a showing of good cause, usually for technology problems related to CARS. In this event, the applicant should submit a request to extend the submission deadline via email to the CPRIT Helpdesk within 8 hours of the submission deadline. If CPRIT approves the applicant's request for extension, then CPRIT will reopen CARS for a 2-hour window to allow an applicant with an unsubmitted application to complete and submit it. CPRIT will document submission deadline extensions, including the reason for the extension, as part of the grant review process records.

CPRIT urges applicants to initiate the registration process in CARS several business days prior to deadline to ensure enough time to complete and apply. The applicant's failure to adequately review application instructions and plan accordingly to avoid unexpected issues is not sufficient grounds to justify approval for a late submission.

6.5. Product Development Review Fee for Full Applications

All applicants submitting a full application must pay a nonrefundable fee of $1,000 to partially offset the cost of reviewing Product Development Award applications. The application review fee must be postmarked by the full application submission deadline unless CPRIT approves a

request to submit the fee after the deadline. Applicants should only submit an application fee after an official invitation to submit a full application has been issued from CPRIT.

Applicants should make the payment by check or money order payable to "Cancer Prevention and Research Institute of Texas." On the check or money order, please indicate the full grant application ID and the name of the applicant (PI) of the application. CPRIT cannot accept electronic or credit card payments.

Applicants using the US Postal Service to mail the application review fee should send it to CPRIT's PO Box (see address below). **DO NOT** use CPRIT's physical address when mailing checks via the US Postal Service.

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

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

For those applicants using a delivery service (eg, FedEx, UPS) to send the application review fee, CPRIT's physical address is as follows:

Cancer Prevention and Research Institute of Texas
Wm B Travis State Office Building
1701 N Congress Ave Ste 6-127
Austin, TX 78701

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

7. PRELIMINARY APPLICATION COMPONENTS

CPRIT strongly advises applicants to attend the webinar offered by CPRIT before applying (https://cprit.texas.gov/news-events/webinars/).

7.1. Abstract (maximum 1,500 characters)

Explain the question or problem to be addressed and the approach to its answer or solution. The aims of the application should 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 an

impact on cancer. Describe the unmet medical need addressed by the proposed project. Briefly explain the product, service, technology, or infrastructure proposed and funding needs. Note that the character limit includes spaces.

7.2. Executive Summary (maximum 2 pages)

The Executive Summary should demonstrate the applicant's ability to think strategically and to orchestrate the execution of key operational aspects of device or diagnostic development. Listed below are some key elements to address in the Executive Summary. CPRIT encourages applicants to provide concise responses in bulleted format.

a. Company location and year of incorporation
b. Brief description of the device or diagnostic test
c. Unmet medical need, including clear description of the expected clinical use criteria and resulting impact on clinical pathway
d. Proof of concept, including clear description of rationale for design of studies, as well as choice of any algorithms/software (eg, AI/ML) used to process data
e. Product validation, including clear rationale for statistical interpretation of any algorithms/software (eg, AI/ML) used to process data from studies, leading to resulting projected clinical performance expectations
f. Safety characterization to date
g. Manufacturing development status
h. Regulatory status and plan (eg, brief summary of agency interactions to date, **including any communications with a regulatory agency, US or foreign,** and planned, likely regulatory paths)
i. High-level overview of work to be done during the grant, including key milestones and budget estimates by year
j. Competition
k. Management team
l. Company financial status/fundraising plans
m. Commitment to Texas

7.3. Slide Presentation (maximum 16 slides)

Provide a slide presentation summarizing the proposed project, scientific support, and management team. The slides should succinctly capture all essential elements of the proposed project and should be sufficiently encompassing to be a standalone document. Submit the presentation in PDF format, with 1 slide filling each landscape-orientated page.

7.4. Proposed Project Aims and Budget (maximum 1 page)

Succinctly describe the aims of the proposed project. Provide an anticipated budget request for the project, linking the aims to expected budget amounts. Should CPRIT invite the applicant to submit a full application, the proposed aims and budget will serve as the basis for the project G&Os and requested budget.

7.5. Resubmission Summary (maximum 1 page)

If the applicant submitted a preliminary or full application to CPRIT in previous fiscal years, upload a brief summary of the revised approach, including a summary of the applicant's response to specific feedback. The Resubmission Summary is distinct from the Executive Summary. Clearly indicate to reviewers how the applicant has improved the proposal in response to the critiques from CPRIT. In the Resubmission Summary, refer to specific sections in the resubmission where the reviewer may find further detail on the questions and feedback to the original application.

Responsiveness to previous critiques is a factor in the review. However, reviewers will assess and score the resubmission as a whole, not solely based on improvement and progress made. The review panel for the resubmission may differ from the previous review panel.

8. FULL APPLICATION COMPONENTS

CPRIT does not require or request letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc. Do not submit letters of support as part of your preliminary or full application package. CPRIT will remove any such information from your application before review. Applicants should minimize repetition among application components to the extent possible and use discretion when cross-referencing sections to maximize the amount of information presented within the page limits. Note that where character limits are specified, spaces are included in the character limit.

8.1. Abstract and Significance (maximum 5,000 characters)

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.

8.2. Layperson's Summary (maximum 1,500 characters)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Explain how the proposed project supports CPRIT's statutory mission. For example, will the project fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Will it synergize with Texas-based resources? Address how the company's work, if successful, may have a major impact on the care of patients with cancer.

Do not include any proprietary information in this section because CPRIT makes the Layperson's Summary publicly available (eg, posted on CPRIT's public website) if the company receives CPRIT funding.

Advocate reviewers use the Layperson's Summary when evaluating the significance and impact of the proposed work.

The Layperson Summary should describe the following:

a. How the proposed project specifically supports CPRIT's mission
b. The overall goals of the work
c. The type(s) of cancer addressed
d. The potential significance of the results
e. The impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer

f. How the company's work, if successful, may have a major impact on the care of patients with cancer

8.3. Goals and Objectives (G&Os) (maximum of 1,200 characters each)

List specific G&Os for each year of the project. G&Os should be clearly delineated, realistic, and consistent with the IPDP and timeline to allow for unambiguous measurement of progress. While the G&Os may be more detailed than the proposed project aims included in the applicant's preliminary application, the G&Os should not vary significantly from the proposed project aims.

The G&Os are a fundamental aspect of the application; applicants should carefully consider and justify each proposed G&O. CPRIT will incorporate the G&Os into the award contract and will use the G&Os to evaluate progress of the funded project. Demonstrating the timely and successful achievement of G&Os is necessary before CPRIT will advance the next tranche of funding. While it is laudable to pursue aggressive goals, failure to achieve a goal or objective during the specified time will result in CPRIT withholding funds until the company can show that the company has completed the outstanding issue.

NOTE: CPRIT and the company may negotiate a contractual change to 1 or more of the G&Os during the funded project as scientific progress and development activities dictate; however, material changes will require substantial justification because the G&Os are the foundation of the funding decision by CPRIT.

8.4. Executive Summary (maximum 2 pages)

The Executive Summary should demonstrate the applicant's ability both to think strategically and to orchestrate the execution of key operational aspects of device or diagnostic development. Listed below are some key elements to address in the Executive Summary. CPRIT encourages applicants to provide concise responses in bulleted format. NOTE: The applicant may submit the same Executive Summary it provided in its preliminary application or may update it, as necessary.

a. Company location and year of incorporation
b. Brief description of the device or diagnostic test
c. Unmet medical need, including clear description of the expected clinical use criteria and resulting impact on clinical pathway

d. Proof of concept, including clear description of rationale for design of studies, as well as choice of any algorithms/software (eg, AI/ML) used to process data
e. Product validation, including clear rationale for statistical interpretation of any algorithms/software (eg, AI/ML) used to process data from studies, leading to resulting projected clinical performance expectations
f. Safety characterization to date
g. Manufacturing development status
h. Regulatory status and plan (eg, brief summary of agency interactions to date, **including any communications with a regulatory agency, US or foreign,** and planned, likely regulatory paths)
i. High-level overview of work to done during the grant, including key milestones and budget estimates by year
j. Competition
k. Management team
l. Company financial status/fundraising plans
m. Commitment to Texas

8.5. Timeline (maximum 1 page)

Provide a visual depiction of anticipated major milestones 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. CPRIT will include the timeline in the executed contract. An applicant should avoid including information that it considers confidential or proprietary in this section.

If the IPDP (see section 8.8) incorporates or depends on results from parallel studies or development programs that CPRIT is not funding, the Gantt chart/timeline should reference these studies, their timelines, and the contingencies they create or resolve with the studies and G&Os funded by CPRIT.

CPRIT will review timelines for reasonableness. Applicants should provide realistic timelines because the G&Os link directly to the timeline. If CPRIT approves the application for funding, the award contract will include the approved timeline. Adherence to timelines is a criterion for continued support of successful applications.

8.6. Slide Presentation (maximum 10 slides)

Provide a slide presentation summarizing the application. Submit the presentation in PDF format, with 1 slide filling each landscape-orientated page. The slides should succinctly capture all essential elements of the application and should be sufficiently encompassing to be a standalone document.

8.7. Resubmission Summary (maximum 2 pages)

If the applicant submitted a preliminary or full application to CPRIT in previous fiscal years, upload a summary of the revised approach, including a summary of the applicant's response to specific feedback. The Resubmission Summary is distinct from the Executive Summary. Clearly indicate to reviewers how the applicant has improved the proposal in response to the critiques from CPRIT. In the Resubmission Summary, refer to specific sections in the resubmission where the reviewer may find further detail on the questions and feedback to the original application.

Responsiveness to previous critiques is a factor in the review. However, reviewers will assess and score the resubmission as a whole, not solely based on improvement and progress made. The review panel for the resubmission may differ from the previous review panel.

8.8. Integrated Product Development Plan (IPDP) (maximum 12 pages)

8.8.1. Overview

An IPDP consists of the following:

a. The work already done that substantiates the rationale and lays the foundation for the work proposed in the application
b. The detailed development plan and proposed work over the duration of the application
c. The design, production, manufacturing, and controls plan
d. The regulatory activities and timelines associated with each plan
e. Copies of all communications with any regulatory agency, US or foreign

The IPDP should be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, data should drive the IPDP.

A comprehensive IPDP includes information for clinical, nonclinical, and manufacturing studies through marketing application along with any regulatory strategies. It should allow the applicant to construct a detailed timeline (eg, Gantt chart) incorporating the different disciplinary studies

into 1 cohesive document to allow for assessment of risks if studies are incomplete by the original timeline. Reviewers will assess the accuracy of proposed timelines for conduct of clinical studies evaluating anticipated rates of recruitment considering any competing clinical studies, completion of nonclinical studies prior to regulatory submissions, and adequacy of any required assay development supporting the development of the medical diagnostic or medical device.

The IPDP also demonstrates the applicant's thorough grasp of the risks associated with their development program. Inclusion of go/no-go decision points assists the reviewers when evaluating the commercial astuteness of the applicant. The applicant should supplement this information with appropriate market entry strategy considering both the current competitive landscape as well as competitive products in development.

Applicants may provide references for the IPDP section as a standalone document that the applicant will separately upload into CARS. In the interest of brevity, include only the most pertinent and current literature. While references will not count toward the IPDP section page limit, it is essential to be concise and to select only those references relevant to the IPDP. Do not use the references to circumvent IPDP section page limits by including data analysis or other nonbibliographic material.

This section highlights components of the IPDP that are of fundamental importance during the peer review and scoring process. Please note that this may not be all inclusive. When addressing future work, use the appropriate sections below as guidance. CPRIT recognizes that applications addressing early-stage research may not have information for all sections.

8.8.2. Target Product Profile (TPP)

A target product profile (TPP) that projects a clear path to full commercialization is essential to a solid IPDP. The TPP serves as a summary of the product development program described in terms of a marketed label with supporting data. It includes information on conducted and planned studies and serves to facilitate the company's interactions with regulatory authorities. The comprehensive TPP may also include commercial information, IP positions, and ultimately go/no-go decision criteria to determine whether a product development program should proceed or end. NOTE: While the TPP for a PMA will be more elaborate than one for 510(k), CPRIT requires a TPP for all products proposed for development in the application.

Because the TPP is an abstract of the IPDP, CPRIT encourages the applicant to complete the TPP prior to drafting the IPDP. The applicant may employ a basic or comprehensive approach to the TPP. Many companies follow the format based on the Medical Device and In Vitro Diagnostic labeling guidance (https://www.fda.gov/media/74034/download) to create the TPP.

CPRIT considers the following topics appropriate for a comprehensive TPP:

Diagnostic Commercialization

a. Type of diagnostic product: molecular/cellular/imaging markers (referred to as "markers" or "biomarkers") and assays for cancer detection, diagnosis, prognosis, monitoring, and prediction of response or resistance to treatment; markers for cancer prevention and control; companion diagnostic to a therapy; development of diagnostic tests to distinguish high-risk early lesions from less risky cancers; development and/or clinical validation of analytical assays to be used in cancer treatment, control, or prevention trials; validation of pharmacodynamic markers and markers of toxicity

Applicants should have assays that work on human samples and whose importance is well justified for development into clinical assays. As clinicians often combine chemotherapies and/or radiation therapies with immunotherapies to enhance durability of anticancer responses, assays for measuring multiple markers, including immune markers, can be developed and validated simultaneously.

Device Commercialization

a. Type of device, including pictorial representations of each of the functional components or elements of the device if the device consists of more than 1 physical component or element; the principles of operation of the device.
b. The methods, facilities, and controls used in the manufacture, processing, packing, storage, and where appropriate, installation of the device in sufficient detail so that a person generally familiar with current good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.
c. Intended uses: treatment, therapeutic treatment decision, detection, diagnosis, prognosis, prediction, monitoring.
d. Unmet need.
e. Stage of development of the product: proof of concept, prototype, validation, clinical

f. Product validation: describe nonclinical and clinical trial data and designs intended to demonstrate device use and/or diagnostic effects.
g. Manufacturing of prototype, scaleup, commercial scale:
    1) Type and methods for quality measurement planned in QA/QC.
    2) Assessment of quality versus cost (cost of goods [COGs] below) at expected. commercial scale.
h. Regulatory pathway: 510(k), PMA.
i. Completed and planned studies for marketing approval, if applicable:
    1) Performance testing to establish substantial equivalence with a predicate device.
    2) Proposed labeling.
    3) Safety characterization to date.
    4) Manufacturing development status.
    5) Clinical trial status and plans forward covered by the grant..
    6) Biocompatibility of any patient contacting materials.
    7) EMC and electrical safety of medical devices incorporating electronic components.
    8) Software documentation for devices containing or utilizing software.
    9) Verification and validation of sterilization and shelf life.
    10) Summary of nonclinical laboratory studies.
    11) Summary of the clinical investigations including a discussion of subject selection and exclusion criteria, study population demographics, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, device failures and replacements.
j. IP
k. Licensing agreements.
l. Competitive analysis.
m. Commercialization pathway and strategy:
    1) Target COGs.
    2) Reimbursement strategy.

8.8.3. Product Validation

a. Describe the independent validation of the product through external work by associates or competitors. If the product detects or measures biomarkers, demonstrate or cite to what

extent the biomarkers have been validated, eg, through knockdown studies and/or measuring expression in disease models or patients' samples.

b. Describe the robustness of the development process to include accuracy; specificity and precision of any nonclinical, clinical, and analytical assays; and the uniqueness of the target in cancer cells.
c. Document the compliance of your process and materials regarding International Organization for Standardization standards and good manufacturing processes. Provide a clear summary describing the stage of product development (fully validated, prototyped, tested in clinical setting) with emphasis on demonstration of proof of principle, and if clinical studies are required, adequate data summaries for conducted studies or detailed design elements for future studies.

8.8.4. Clinical Study Development Plan

If the company proposes to carry out clinical studies with CPRIT funds, such studies must include scientifically valid designs, regulatory validated clinical end points, appropriate patient population and sample size, adequate duration of exposure and follow-up, and regulatory acceptable controls.

NOTE: As set forth in section 8.8.6, the applicant must provide any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application.

Describe the study design, including the following information:

a. Patient population, including the case and control groups (if applicable). The applicant should document the inclusion and exclusion criteria for the trial, explain the appropriateness of patient populations from a safety perspective, and justify the generalizability of results to TPP patient population.
b. Randomization scheme and/or comparator/control arm. In the case of controls, justify the choice of control.
c. Justification for clinical trial sample size including statistical considerations.

d. Justification of target efficacy effect size if applicable, eg, if the company intends the study to support accelerated approval, general approval, or inform go/no-go decision-making.
e. Discuss clinical relevance of target effect size.
f. Adaptive study designs (Bayesian or frequentist) should be clear on design criteria and clinical rationale. For sequential designs with interim analyses, define the impact on design criteria and power. Also define relevant stopping rules and related justification of expected clinical performance criteria.
g. Study implementation information describing the number of investigational sites and the estimated patients enrolled per site. Explain whether the site has competing study protocols and how this will impact accrual. Describe the incidence/numbers of patients meeting patient population description per site. Discuss initiatives the company plans to address recruitment challenges. Detail the study activities that the company will contract out versus activities it will manage internally. Demonstrate that relevant clinical operations experience is present within the study team.
h. Study timeline, including key startup activities (see below).
i. Study budget broken down by major cost/driver areas, and a fully inclusive figure representing the total study budget.
j. Describe the extent of contract research organization (CRO) input into budget preparation and include any quotations/estimates from any CROs or other third parties providing clinical trial services in the Budget Justification (see section 8.12).

8.8.5. Regulatory Plan

Regulatory input on the company's TPP is critical to finalize the clinical, nonclinical, and manufacturing studies that define the IPDP. While companies may plan an exit strategy prior to bringing a product to late-stage development or to the market, the development and adherence to a logical, expeditious, and fully integrated regulatory plan are advisable to maximize value for any potential purchaser.

Accordingly, the Regulatory Plan is an important part of the CPRIT application and an opportunity for the successful applicant to demonstrate proficiency and expertise. In detailing the proposed regulatory plan, the applicant should address the following considerations and topics:

a. Identify the point of contact with regulatory authorities. The individual communicating with the FDA should have experience and a successful track record interacting with regulatory authorities, preferably having brought products to the market.
b. The timing of development meetings with regulatory authorities.

8.8.6. Regulatory Correspondence Documentation

Applicants must upload as a standalone document copies of any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (eg, FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application. This is a continuing obligation that extends over the course of the review process. If the applicant receives meeting minutes after submitting the application but before CPRIT has made a final decision on the application, the applicant should contact the CPRIT Helpdesk (see section 10.1) for assistance on filing the additional information.

8.8.7. Design/Production/Manufacturing

The applicant must have sufficient expertise and resources to address necessary design, production, and manufacturing activities, including scaling up in preparation of the documentation required for the IDE submission and, eventually, the 510(k) or PMA. The applicant should consider enlisting the services of an individual who has been responsible for the successful development of several products that have attained marketing approval.

The individual(s) responsible for the manufacture of the medical device or diagnostic must ensure that the proposed G&Os are in line with the state of the development of the product. The timelines for the development of the product must be reasonable and realistic with appropriate assessments of risks and risk management plans to address potential risks. Applicants should explain the commercialization of the product and a comprehensive description of the anticipated COGs, including the program management of anticipated contractors and the sourcing of raw materials, reagents, supplies, and instruments.

8.9. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies must raise substantial funds from other sources to fully fund development. Investors seek financial returns on their investment. An applicant should convince CPRIT that

this project has investment return potential based on its risk profile sufficient to raise external capital.

CPRIT review typically focuses on size of market opportunity, development path, and key risk issues. The reviewers will evaluate company applicants based not only on the status of the components of the business plan but also on whether the company acknowledges current weaknesses and gaps and outlines a plan to address them.

The business plan consists of the business rationale overview and summaries of the following key development issues listed below. The business plan section may request some of the information that the applicant has included in the IPDP. To the extent possible, avoid duplication, redundancy, or references to the IPDP in favor of summarizing the information in the business plan.

8.9.1. Business Rationale (maximum 2 pages)

Provide the business rationale for investing in this project. Successful applicants will provide a thoughtful, careful, and succinct business justification explaining why this project is an appropriate investment of CPRIT and private funds.

8.9.2. Product and Market (maximum 1 page)

While the applicant will also provide information on the product and potential market when creating the IPDP required pursuant to section 8.8, including an overview of the product and method of delivery, describing the unmet medical need, and explaining the potential market in this section provide context for rest of the business plan.

a. Explain the unmet medical need with particular focus on patient populations contemplated for initial target indication(s): incidence/prevalence, life expectancy/survival, morbidity, annual mortality figures. Assuming the successful achievement of development objectives, describe how the intended product significantly addresses an unmet medical need in the diagnosis and/or treatment (including supportive care) and prognosis, or prevention of cancer.
b. Describe the initial target market and how the product fits within the standard of care (SOC), ie, how the innovative product will impact the clinical care pathway, both in terms of the criteria of use/adoption as well as the downstream clinical impact. This will range from innovations that will displace existing diagnostics/devices through superior

performance in current SOC pathways, to diagnostic/device innovations that create novel, improved clinical pathways with different decision processes for improved patient outcomes. Patient populations should be broadly comparable to those included in the pivotal trials. Define patient population sizes by market segments.

8.9.3. Competition and Value Proposition (maximum 1 page)

a. Provide an overview of the competitive environment (current and anticipated) and how the envisioned product will compete in the marketplace.
b. Analyze the strengths and weaknesses of the proposed product compared to current and potential future products, including any significant improvements over the current SOC such as a better safety profile, reduced costs, improved compliance, and improved convenience. A clear delineation of competitive advantages, including supporting summary data, is important.

8.9.4. Clinical and Regulatory Plans (maximum 1 page)

Provide an overview of the regulatory strategy, including preclinical and clinical activities and the regulatory pathway for major markets.

a. Include summary descriptions of regulatory communications (including all interactions to date with the FDA) and a description of how the company incorporated feedback from regulatory authorities.
b. If the application includes clinical research, present a plan to achieve realistic accrual rates of patients that meet the inclusion/exclusion criteria within the proposed timeline.

8.9.5. Pricing and Reimbursement (maximum 1 page)

Provide an overview of the projected 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. An excellent application will include financial modeling on expected clinical pathway cost changes over populations indicated for an innovative diagnostic or device application, and such cost changes will be analyzed with respect to clinical benefit to anticipate insurance/reimbursement decisions. In particular, depending on clinical application, reimbursement for diagnostics can be highly sensitive to false-positive and false-negative statistical performance rates, and these should be addressed as applicable.

8.9.6. Commercial Strategy (maximum 1 page)

Provide an overview of the company's financial projections and how the company plans to generate a return on this investment.

a. Describe how the company plans to bring the product to market. Information on targeted physicians, sales channels, etc, is helpful.
b. Alternatively, if the company's plan includes acquisition by a larger medical device/pharmaceutical/HIT company, etc, provide an overview of similar transactions.

8.9.7. Risk Analysis (maximum 1 page)

Describe the specific risks inherent to the product plan and how the company plans to mitigate those risks. Key risk issues typically include efficacy versus competitors, clinical trial implementation and conduct, FDA approval, production and manufacturing, changing competitive environment, etc.

8.9.8. Funding to Date (this section may exceed 1 page, if necessary)

Provide an overview of the funding received by the company, including a list of funding sources and a comprehensive capitalization table that comprises all parties with investments, stock, or rights in the company. CPRIT provides a template for a capitalization table in the application materials that the applicant **must** use when completing the application. The applicant must list identities of all parties and may exceed the 1-page limit if necessary to fully capture all funding sources. It is not appropriate to list any funding source as anonymous.

8.9.9. Company Financial Overview (maximum 1 page)

Please describe the company's financial condition including cash on hand, runway, burn rate, expenses, debt, working capital and any other metric that would provide insight into the company's finances.

8.9.10. Intellectual Property (IP)/Freedom to Operate (maximum 1 page)

a. List patents/patent applications together with jurisdictions, ownership/licensing aspects, status, and filing and expiration dates.
b. Indicate by patent/patent application the nature of key claims, viz, COM, methods, uses, sample/tissue/cell prep process IP, material science IP for devices, etc, and what specifically would such claims prevent a competitor from doing. In this respect, include a

discussion of the ease of workaround by a potential competitor. For any algorithm and/or software components key to differentiated competitive performance of a diagnostic or device, please clearly discuss trade-off and decisions regarding trade secret, copyright, and IP to protect against competitive threats.

c. For future/anticipated patent filings, indicate whether such filings will be continuation in part as opposed to divisional or novel/standalone patents.
d. Discuss potential for exclusivity as well as the potential contribution of trade secrets to protection from competition.
e. Describe freedom to operate, licensing status/plans.

8.9.11. Management Team and Key Personnel (maximum 1 page)

The applicant's management team should be composed of individuals who have the appropriate level of experience in developing and commercializing products. The team should include appropriate disciplinary experts in product engineering, clinical development, nonclinical development, product design, manufacturing, regulatory strategy, commercialization, and fundraising. An experienced program manager who has coordinated product development activities to product approval is desired. Team members, either consultants or company employees, must have sufficient time to devote to development activities allocated in the application.

For each member of the senior management and scientific team, provide a paragraph summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Also indicate the percentage of the person's time devoted to the project. The time indicated by the company is an obligatory commitment, regardless of whether 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.

Provide the same information for other key personnel 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.) NOTE: While the applicant should

identify all participants who meet these criteria as "key personnel," CPRIT expects that the applicant will keep to a minimum the number individuals designated as key personnel.

8.10. Biographical Sketches of Key Scientific Personnel (maximum 8 pages)

Provide a biographical sketch for up to 4 key scientific personnel describing their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. CPRIT provides an optional "Product Development Research Programs: Biographical Sketch" template for the applicant's use. The NIH biographical sketch format is also appropriate.

8.11. Commitment to Texas (maximum 1 page)

Describe the company's commitment to locating in Texas and maintaining its business presence in the state. Please identify the criteria specified in section 4.1 "Award Recipients Must Be Texas-Based, For-Profit Companies" that the company will fulfill if it receives a CPRIT award.

If the applicant is not currently Texas based, provide a timetable with key dates indicating the applicant's plan and commitment to relocate the company to Texas. In addition, describe which personnel and management will be headquartered in Texas.

8.12. Budget

This is a 3-year funding program, with an opportunity to extend the duration of contract to fully expend awarded funds. All requested funds must be well justified; CPRIT will award financial support based upon the breadth and nature of the project proposed, the transparency of the budget, and the extent to which the company will spend funds in Texas. The total budget included in the full application must not vary significantly from the anticipated budget request included in the applicant's preliminary application. For purposes of this section, "vary significantly" means that the total budget in the full application must not exceed the anticipated budget request in the preliminary application by more than 5%.

The budget must align with the proposed G&Os. CPRIT will disburse funds in tranches tied to the company's achievement of the contractual G&Os.

When preparing the requested budget, applicants should consider the following:

a. Identify the specific equipment that the company proposes to purchase with grant funds. Items that the company includes in the "equipment" budget line should have a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit.
b. Texas Health and Safety Code Section 102.203(d) limits the amount of grant funds that companies may spend on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). CPRIT's Administrative Rules provide guidance regarding indirect cost recovery.
c. The total amount of CPRIT funds allowed for an individual's FY25 annual salary is $225,000. An individual may request salary proportional to the percent effort up to a maximum of $225,000. Companies may pay salary amounts exceeding this limit from matching funds. The salary amount does not include fringe benefits. Additionally, CPRIT permits annual salary adjustments of up to a 3% increase for Years 2 and 3, up to the cap of $225,000. CPRIT may revise the FY25 salary cap and future salary caps at its discretion.

The Budget section is composed of 4 subtabs:

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 the company requests funding for a role that the company has not yet filled at the time of submission, the applicant should note "new hire" as name.
b. **Detailed Budget for Year 1:** 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. This section should include only the amount requested from CPRIT. DO NOT include the amount of the matching funds or the budget for the entire proposed period of performance.
c. **Budget for Entire Proposed Period of Performance:** Provide the amount requested from CPRIT for direct costs for all subsequent years. CARS will automatically populate the amounts for *Budget Year 1* based on the information provided in the previous subtabs. This section should include only the amount requested from CPRIT. DO NOT include the amount of the matching funds.
d. **Budget Justification:** The budget should align with the proposed G&Os. 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. For projects that involve CROs or other third parties providing clinical trial services, include quotations/estimates from the CRO/other third parties. If travel costs will include out-of-state or international travel, make that clear here. This section should include CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds.

9. AWARD CONTRACTS

9.1. Overview

Texas law requires that CPRIT award grant funds via a contract between the company and CPRIT. Contract negotiation commences after the CPRIT Oversight Committee votes to approve an application for a grant award. Texas law specifies several contract terms that CPRIT must include in the executed agreement, including terms relating to revenue sharing and IP rights, matching funds, and required reporting for fiscal, progress, and compliance.

CPRIT recommends that applicants review CPRIT's Administrative Rules and its related Policies & Procedures Guide (available at www.cprit.texas.gov) for information describing contractual requirements, fiscal and program progress reporting, and limitations on the use of CPRIT grant funds. This RFA highlights information regarding revenue sharing and matching funds below.

9.2. Revenue-Sharing Terms

The contract will include a revenue-sharing agreement. CPRIT publishes its standard revenue-sharing terms on its website at https://cprit.texas.gov/our-programs/product-development-research. CPRIT will include these standard revenue-sharing terms in the award contract unless parties negotiate different revenue-sharing terms that are in the interest of the state and the company.

9.3. Matching Funds

CPRIT requires a company receiving a CPRIT Product Development Research Award to pay a portion of the overall project expenses using money under the company's control. The company's expenditure of these "matching funds" must take place at the same time the company is drawing down CPRIT funds; there is no credit toward the CPRIT matching funds requirement

for in-kind expenses or expenditures made prior to the CPRIT award. The company may fulfill its matching funds commitment on a year-by-year basis.

The company demonstrates that it has available matching funds when CPRIT disburses funds pursuant to an executed award contract, not when the company submits the CPRIT application.

CPRIT sets the amount of matching funds the company must contribute toward the project based on the total amount of CPRIT funds committed to the company:

- For companies receiving $20 million or less from CPRIT (inclusive of previous CPRIT awards), the company must dedicate to the project at least $1 of funds under the company's control for every $2 of CPRIT grant award funds.
- A company approved for 1 or more CPRIT product development grants that together total a commitment of more than $20 million must increase their matching fund obligation to at least $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 CPRIT's matching funds policy, the company must dedicate at least $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 1 or more CPRIT product development grants that together total a commitment of more than $30 million must contribute at least $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.

10. CONTACT INFORMATION

10.1. Helpdesk

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration and online submission of applications. Helpdesk staff cannot 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. For "Frequently Asked Technical Questions," please go here.

Hours of operation:	Monday through Friday, 8:00 AM to 6:00 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

10.2. Programmatic Questions

The CPRIT Product Development Program Manager will answer questions regarding CPRIT's Product Development Program awards and review process, including questions regarding the scientific, product development, and business aspects of applications. For "Frequently Asked Programmatic Questions," please go here.

Tel:	512-305-7676
Email:	proddev@cprit.texas.gov
Website:	www.cprit.texas.gov

11. APPENDIX - REVIEWER EVALUATION GUIDELINES

11.1. Primary Review Criteria (Scored)

11.1.1. Unmet Medical Need

a. 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?
b. 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?

11.1.2. Product Validation

a. Technical validation: Has the product or technology been successfully validated, ie, prototyped, built, and tested in ex vivo, animal, or clinical setting?
b. Have biological proof of principle and product mechanism of action been demonstrated?
c. Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
d. Clinical validation: Are clinical trials required to demonstrate product performance? If so, have they been planned or conducted?
e. Biological risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

11.1.3. Production/Manufacturing

a. Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable COGs?
b. How advanced is manufacturing development?
c. Are there any sourcing issues?

11.1.4 Intellectual Property (IP)/Freedom to Operate

a. Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique know-how?
b. Does the company have issued patents? If not, have they conducted freedom-to-operate and patentability analysis?
c. Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?

d. Are there opportunities for meaningful patent life extension?
e. Has the applicant secured appropriate licenses conferring freedom to operate, if required?

11.1.5 Market Opportunity

a. Does the product address a clearly defined unmet need, eg, lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?
b. Are target indication and market clearly defined?
c. Is a channel to market available? Does the company understand the entire value chain and all constituencies involved in procuring and utilizing the product?
d. Does the company understand the clinical pathway that leads to utilizing the product?
e. Is market opportunity of significant size and lucrative enough to justify investment?
f. Has the applicant demonstrated time or cost savings?
g. How does product fit with existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

11.1.6 Competition

a. Is this a "whole product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
b. Is value proposition clearly delineated, ie, improve efficacy, improve safety, reduce cost, or improve convenience?
c. Has the company demonstrated its value proposition versus competition?
d. 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?

11.1.7 Development Plan/Regulatory Aspects

a. Have a comprehensive development plan and market entry strategy been developed? How realistic are these plans?
b. Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

11.1.8 Management Team

a. Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
b. 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?
c. Has the applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

11.1.9 Business/Commercial Aspects

a. 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?
b. 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?
c. Has the company clearly anticipated pricing strategy and reimbursement environment?
d. Is the projected return on investment congruent with investment opportunity and risks?

11.1.10 Funding

a. Is investor interest in this sector sufficient to fund the company through profitability?
b. 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?
c. Have likely acquirers been identified by the applicant?
d. Does the company have the resources to support required activities while fundraising?
e. 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?

11.2. Secondary Review Criteria (Unscored) - Budget and Duration of Support

a. Are the budget and duration of support appropriate for the program of studies described in the application?
b. Is there sufficient clarity in the budget proposal as to how funds will be expended?
c. Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
d. 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)
FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6)
Observation Report

Report No.	2024-06-10 PDPRE - 25-1.6
Program Name:	Product Development Research
Panel Name:	FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6)
Panel Date:	June 10, 2024
Report Date:	June 13, 2024

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 FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on June 10, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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: Four (4)
- 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.

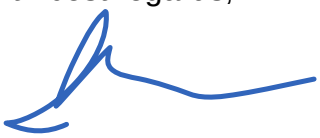
CONCLUSION

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.

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, CRMA, 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)
FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.1
Program Name:	Product Development Research
Panel Name:	FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1) meeting. The meeting was chaired by Kristine Swiderek and conducted via videoconference on June 12, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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 was one (1) Conflict 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, CRMA, 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)
FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.3
Program Name:	Product Development Research
Panel Name:	FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3) meeting. The meeting was chaired by Renzo Canetta and conducted via videoconference on June 12, 2024.

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
- Panelists: One (1) discussion lead and three (3) expert 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 was one (1) 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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.5
Program Name:	Product Development Research
Panel Name:	FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5) meeting. The meeting was chaired by Roy Cosan and conducted via videoconference on June 12, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) application were discussed and seven (7) applications were not discussed
- Panelists: One (1) discussion lead, and three (3) expert 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 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, CRMA, 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)
FYFY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2)
Observation Report

Report No.	2024-06-13 PDPRE-25-1.2
Program Name:	Product Development Research
Panel Name:	FY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2)
Panel Date:	June 13, 2024
Report Date:	June 18, 2024

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 FY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on June 13, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead and three (3) expert 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 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,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8)
Observation Report

Report No.	2024-06-14 PDPRE-25-1.8
Program Name:	Product Development Research
Panel Name:	FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8)
Panel Date:	June 14, 2024
Report Date:	June 18, 2024

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 FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on June 14, 2024.

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: Three (3) application were discussed and eight (8) applications were not discussed
- Panelists: One (1) discussion lead and three (3) expert 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 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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With best regards,

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

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9)
Observation Report

Report No.	2024-06-18 PDPRE-25-1.9
Program Name:	Product Development Research
Panel Name:	FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9)
Panel Date:	June 18, 2024
Report Date:	June 21, 2024

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 FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on June 18, 2024.

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: Eleven (11) applications were discussed
- Panelists: One (1) discussion lead, and three (3) expert 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 was one (1) Conflict 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, CRMA, 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)
FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7)
Observation Report

Report No.	2024-06-20 PDPRE-25-1.7
Program Name:	Product Development Research
Panel Name:	FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7)
Panel Date:	June 20, 2024
Report Date:	June 21, 2024

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 FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on June 20, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed and eight (8) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-1 (25.1 _PDP-1)
Observation Report

Report No.	2024-09-06 25.1_PDP-1
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-1 (25.1 _PDP-1)
Panel Date:	September 6, 2024
Report Date:	September 9, 2024

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 25.1 Product Development Panel-1 (25.1_PDP-1) meeting. The meeting was chaired by Tian Yu and conducted via videoconference on September 6, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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, CRMA, 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)
25.1 Product Development Panel-2 (25.1_PDP-2)
Observation Report

Report No.	2024-09-09 25.1_PDP-2
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-2 (25.1 _PDP-2)
Panel Date:	September 9, 2024
Report Date:	September 10, 2024

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 25.1 Product Development Panel-2 (25.1_PDP-2) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on September 9, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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: Three (3)
- 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-3 (25.1 _PDP-3)
Observation Report

Report No.	2024-09-09 25.1_PDP-3
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-3 (25.1 _PDP-3)
Panel Date:	September 9, 2024
Report Date:	September 10, 2024

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 25.1 Product Development Panel-3 (25.1_PDP-3) meeting. The meeting was chaired by Renzo Canetta and conducted via videoconference on September 9, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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.

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With best regards,

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

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Product Development Panel-4 (25.1_PDP-4)
Observation Report

Report No.	2024-09-10 25.1_PDP-4
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-4 (25.1 _PDP-4)
Panel Date:	September 10, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-4 (25.1_PDP-4) meeting. The meeting was chaired by Roy Cosan and conducted via videoconference on September 10, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-5 (25.1_PDP-5)
Observation Report

Report No.	2024-09-11 25.1_PDP-5
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-5 (25.1 _PDP-5)
Panel Date:	September 11, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-5 (25.1_PDP-5) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on September 11, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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: Two (2)
- 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-6 (25.1_PDP-6)
Observation Report

Report No.	2024-09-12 25.1_PDP-6
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-6 (25.1 _PDP-6)
Panel Date:	September 12, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-6 (25.1_PDP-6) meeting. The meeting was chaired by David Russler-Germain and conducted via videoconference on September 12, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-7 (25.1 _PDP-7)
Observation Report

Report No.	2024-09-13 25.1_PDP-7
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-7 (25.1 _PDP-7)
Panel Date:	September 13, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-7 (25.1_PDP-7) meeting. The meeting was chaired by Ginette Serrero and conducted via videoconference on September 13, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-8 (25.1 _PDP-8)
Observation Report

Report No.	2024-09-13 25.1_PDP-8
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-8 (25.1 _PDP-8)
Panel Date:	September 13, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-8 (25.1_PDP-8) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on September 13, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-9 (25.1 PDP-9)
Observation Report

Report No.	2024-09-16 25.1_PDP-9
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-9 (25.1 _PDP-9)
Panel Date:	September 16, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-9 (25.1_PDP-9) meeting. The meeting was chaired by Jill Kolesar and conducted via videoconference on September 16, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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 was 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-10 (25.1_PDP-10)
Observation Report

Report No.	2024-09-16 25.1_PDP-10
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-10 (25.1 _PDP-10)
Panel Date:	September 16, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-10 (25.1_PDP-10) meeting. The meeting was chaired by Jun Deng and conducted via videoconference on September 16, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-11 (25.1_PDP-11)
Observation Report

Report No.	2024-09-17 25.1_PDP-11
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-11 (25.1 _PDP-11)
Panel Date:	September 17, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-11 (25.1_PDP-11) meeting. The meeting was chaired by Steven Weinstein and conducted via videoconference on September 17, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-12 (25.1_PDP-12)
Observation Report

Report No.	2024-09-17 25.1_PDP-12
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-12 (25.1 _PDP-12)
Panel Date:	September 17, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-12 (25.1_PDP-12) meeting. The meeting was chaired by Christopher Carpenter and conducted via videoconference on September 17, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-13 (25.1_PDP-13)
Observation Report

Report No.	2024-09-18 25.1_PDP-13
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-13 (25.1 _PDP-13)
Panel Date:	September 18, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-13 (25.1_PDP-13) meeting. The meeting was chaired by William Gmeiner and conducted via videoconference on September 18, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-14 (25.1_PDP-14)
Observation Report

Report No.	2024-09-19 25.1_PDP-14
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-14 (25.1 _PDP-14)
Panel Date:	September 19, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-14 (25.1_PDP-14) meeting. The meeting was chaired by Arnab Ghosh and conducted via videoconference on September 19, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-15 (25.1_PDP-15)
Observation Report

Report No.	2024-09-19 25.1_PDP-15
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-15 (25.1 _PDP-15)
Panel Date:	September 19, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-15 (25.1_PDP-15) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on September 19, 2024.

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) application was discussed
- Panelists: One (1) panel chair, six (6) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-16 (25.1_PDP-16)
Observation Report

Report No.	2024-09-20 25.1_PDP-16
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-16 (25.1 _PDP-16)
Panel Date:	September 20, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-16 (25.1_PDP-16) meeting. The meeting was chaired by Matthew Spear and conducted via videoconference on September 20, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-17 (25.1_PDP-17)
Observation Report

Report No.	2024-09-23 25.1_PDP-17
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-17 (25.1 _PDP-17)
Panel Date:	September 23, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-17 (25.1_PDP-17) meeting. The meeting was chaired by Alan West and conducted via videoconference on September 23, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-18 (25.1_PDP-18)
Observation Report

Report No.	2024-09-24 25.1_PDP-18
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-18 (25.1 _PDP-18)
Panel Date:	September 24, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-18 (25.1_PDP-18) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on September 24, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-19 (25.1_PDP-19)
Observation Report

Report No.	2024-09-25 25.1_PDP-19
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-19 (25.1 _PDP-19)
Panel Date:	September 25, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-19 (25.1_PDP-19) meeting. The meeting was chaired by Kristine Swiderek and conducted via videoconference on September 25, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-20 (25.1_PDP-20)
Observation Report

Report No.	2024-09-26 25.1_PDP-20
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-20 (25.1 _PDP-20)
Panel Date:	September 26, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel-20 (25.1_PDP-20) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on September 26, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: One (1)
- 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, CRMA, 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)
25.1 Product Development Panel - 21 (25.1_PDP - 21)
Observation Report

Report No.	2024-09-26 25.1_PDP - 21
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 21 (25.1 _PDP - 21)
Panel Date:	September 26, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel - 21 (25.1_PDP - 21) meeting. The meeting was chaired by Karen Stein and conducted via videoconference on September 26, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

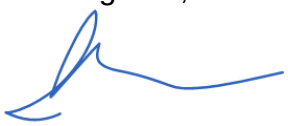
CONCLUSION

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, CRMA, 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)
25.1 Product Development Panel - 22 (25.1_PDP - 22)
Observation Report

Report No.	2024-09-27 25.1_PDP - 22
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 22 (25.1 _PDP - 22)
Panel Date:	September 27, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel - 22 (25.1_PDP - 22) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on September 27, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-7 DD (25.1 PDP-7 DD)
Observation Report

Report No.	2024-10-14 25.1_PDP-7 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-7 DD (25.1 _PDP-7 DD)
Panel Date:	October 14, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-7 DD (25.1_PDP-7 DD) meeting. The meeting was chaired by Ginette Serrero and conducted via videoconference on October 14, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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, CRMA, 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)
25.1 Product Development Panel-9 DD (25.1 PDP-9 DD)
Observation Report

Report No.	2024-10-14 25.1_PDP-9 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-9 DD (25.1 _PDP-9 DD)
Panel Date:	October 14, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-9 DD (25.1_PDP-9 DD) meeting. The meeting was chaired by Jill Kolesar and conducted via videoconference on October 14, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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, CRMA, 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)
25.1 Product Development Panel-5 DD (25.1 PDP-5 DD)
Observation Report

Report No.	2024-10-15 25.1_PDP-5 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-5 DD (25.1 _PDP-5 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-5 DD (25.1_PDP-5 DD) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) and one (1) who remained in the Waiting Room

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.

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With best regards,

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

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT) 25.1 Product Development Panel-6 DD (25.1 PDP-6 DD) Observation Report

Report No.	2024-10-15 25.1_PDP-6 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-6 DD (25.1 _PDP-6 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-6 DD (25.1_PDP-6 DD) meeting. The meeting was chaired by David Russler-Germain and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, and five (5) expert 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Product Development Panel-8 DD (25.1 PDP-8 DD)
Observation Report

Report No.	2024-10-15 25.1_PDP-8 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-8 DD (25.1 _PDP-8 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-8 DD (25.1_PDP-8 DD) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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, CRMA, 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)
25.1 Product Development Panel-12 DD (25.1 PDP-12 DD)
Observation Report

Report No.	2024-10-16 25.1_PDP-12 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-12 DD (25.1 _PDP-12 DD)
Panel Date:	October 16, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-12 DD (25.1_PDP-12 DD) meeting. The meeting was chaired by Christopher Carpenter and conducted via videoconference on October 16, 2024.

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
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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, CRMA, 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)
25.1 Product Development Panel-2 DD (25.1 _PDP-2 DD)
Observation Report

Report No.	2024-10-17 25.1_PDP-2 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-2 DD (25.1 _PDP-2 DD)
Panel Date:	October 17, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-2 DD (25.1_PDP-2 DD) meeting. The meeting was chaired by Collin Turnbull and conducted via videoconference on October 17, 2024.

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
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: One (1)

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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD)
Observation Report

Report No.	2024-10-18 25.1_PDP-20 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD)
Panel Date:	October 18, 2024
Report Date:	October 22, 2024

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 25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on October 18, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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) 25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD)Observation Report

Report No.	2024-10-21 2.51_PDP-22 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD)
Panel Date:	October 21, 2024
Report Date:	October 23, 2024

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 25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on October 21, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- Norton Rose Fulbright Law Firm Consultants staff: Three (3) who remained in the Waiting Room

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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Review Council Meeting (25.1 PDRC)
Observation Report

Report No.	2024-10-28 25.1 PDRC
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Review Council Meeting (25.1 PDRC)
Panel Date:	October 28, 2024
Report Date:	October 30, 2024

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 25.1 Product Development Review Council Meeting (25.1 PDRC) . The meeting was chaired by Jack Geltosky and conducted via videoconference on October 28, 2024.

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: Nine (9) applications were discussed
- Panelists: One (1) panel chair, one (1) panel vice chair, and eight (8) product development review council memebers
- 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 (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.

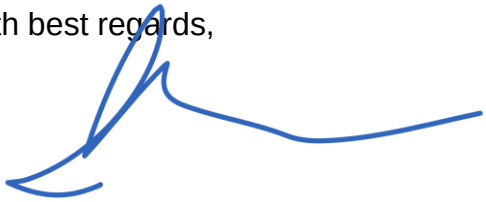
CONCLUSION

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, CRMA, 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 25.1
Awards Announced at the November 20, 2024, Oversight Committee Meeting

The following table 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 25.1 include those received in response to the following Requests for Applications: *SEED Awards for Product Development Research; Texas Diagnostic and Devices Company Awards; Texas Therapeutics Company Awards;* and *Texas New Technology Company 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:			
DP250159	Thapar, Neil C	Barricade Therapeutics, Corp	Rosenfeld, Craig
Applications not considered by the PIC or Oversight Committee:			
DP250115 (preliminary)	Whitney, Duncan	Gregor Diagnostics	Yu, Tian
DP250071 (preliminary)	Li, Yong	SOTLA THERAPEUTICS LLC	Anderson, Karen
DP250075 (preliminary)	Allinson, Bryan	Vanquish Bio	Geltosky, Jack
DP250005 (preliminary)	Carter, Kenneth	Black Canyon Bio, Inc.	Akhavan, David

T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	T.A.C. § 702.19 WAIVER APPROVAL FOR DR. KEN SMITH
DATE:	OCTOBER 29, 2024

Summary

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I have granted Chief Product Development Officer Dr. Ken Smith a waiver from the general prohibition against communicating with a grant applicant while CPRIT is accepting and reviewing applications. The waiver applies to communication with the nine companies that the Product Development Review Council (PDRC) has recommended for grant awards in review cycle 25.1. Approving the waiver promotes CPRIT's objectives and does not give one or more applicants an unfair advantage. No Oversight Committee action related to this waiver is necessary.

Discussion

The Chief Product Development Officer is a statutorily mandated member of the Program Integration Committee (PIC). Texas Administrative Code § 702.19 prohibits substantive communication between the grant applicant and a member of the peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The communication restriction is one way that we prevent even the appearance of unequal treatment in the grant review process. However, the rule provides a process for the CEO to waive the communication restriction in specific circumstances if doing so is in the interest of CPRIT's process and does not give any applicant an unfair advantage.

Approving this waiver allows Dr. Smith to negotiate reductions in proposed budgets with each company prior to Oversight Committee approval. Granting the waiver will not favor any applicant or provide an unfair advantage.

The Oversight Committee does not need to take any action regarding this waiver. Dr. Smith's waiver will be part of the grant record for the FY 2025 product development awards.

High Level Summary of Due Diligence

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Telos Biotechnology for $2,778,945.

No Contingencies

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.

Telos Biotechnology aims to improve CAR T-cell therapy outcomes with TELOVANCE, a telomerase-based treatment that extends telomeres during CAR T-cell manufacturing to delay cell senescence and enhance efficacy. As telomere shortening limits CAR T-cell longevity, TELOVANCE addresses this challenge by selectively extending telomeres in CAR T-cells, improving their therapeutic potential without risk of immortalization.

TELOVANCE's transient telomere extension increases cell survival and cytotoxicity, tackling a key limitation in CAR T-cell therapies, where only 50% of patients achieve long-term remission. This innovation, validated in both in-vitro and in-vivo studies, is positioned to transform CAR T-cell therapy by boosting the performance and durability of the manufactured cells.

The project will transition TELOVANCE production to GMP standards and conduct in-vivo studies for expanded safety testing. Additional studies will explore TELOVANCE's potential in other cell types, expanding its applications beyond hematologic cancers.

CPRIT support will allow Telos to advance TELOVANCE toward commercial readiness and enhance Texas's biotech ecosystem. By establishing a manufacturing presence in Texas, Telos can drive cell therapy innovations and create economic impact through high-value therapeutic developments.

Select Reviewer Comments

"The lack of significant long-term responses in many CAR-T treated patients is a genuine unmet medical need, and Telos is positioned to potentially improve and increase those long-term responses."

"Telovance-treated CAR T-cells showed an increase in persistence six months after injection into mice during pilot safety studies. This is a critically important and clinically relevant result."

"The application proposes the development of an innovative technology that could potentially impact the treatment of cancer and benefit cancer patients greatly. The applicants explain the unique role of Telovance in that it improves the efficacy and durability of cell and gene therapies."

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Ypsilon Therapeutics for $2,727,500.

No Contingencies

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.

Ypsilon Therapeutics is advancing TCR mimic (TCRm) x CD3 antibodies targeting the CT83 peptide, selectively expressed in various solid tumors, to overcome limitations in immune checkpoint inhibitor efficacy. This novel immunotherapy directs T cells to specifically target CT83-expressing tumor cells, enhancing safety and precision.

Leveraging Alloy Therapeutics' TCR discovery platform, Ypsilon has developed TCRm antibodies with high affinity for CT83, engineering them into bispecific CD3 T cell engagers. This approach selectively targets malignant tissues, addressing the unmet need in solid tumor treatment.

This project will develop and validate the TCRm CD3 engagers through bispecific engineering and in-vivo studies in xenograft models, with CPRIT support accelerating preclinical milestones. The project will also facilitate Ypsilon's move to Houston, where they plan to collaborate with MDACC.

CPRIT funding will enable Ypsilon to advance this promising treatment, positioning Texas as a leader in solid tumor immunotherapy and providing new options for patients resistant to existing therapies.

Select Reviewer Comments

"Despite advancements in anti-cancer therapies... the prognosis for patients with solid tumors... continues to be poor. Addressing this need is indeed urgently needed."

"If successful, Ypsilon's bispecific TCRm T cell engager may have a meaningful impact in addressing unmet need. The technologies that result in the first drug could be leveraged to make other engagers that address other HLA and other antigens."

"This proposal, if successful, will result in an innovative product that addresses unmet needs in multiple solid cancers. The upside is significant, and the team is as well-suited to successful execution as any small group could be."

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Erisyon, Inc. for $2,157,172.50

No Contingencies

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.

Erisyon is developing a fluorosequencing-based assay to predict immune checkpoint inhibitor (ICI) resistance in non-small cell lung cancer (NSCLC) patients. By measuring the PSME4 to PSMB10 ratio in immunoproteasomes, this biomarker can identify treatment-resistant tumors, guiding effective therapy selection.

This innovative assay provides absolute molecular quantitation and high sensitivity, enabling accurate antigenicity assessments. With fluorosequencing's capability, Erisyon addresses limitations in current mass spectrometry and antibody assays, enhancing precision in predicting ICI outcomes.

The project will validate the assay's clinical utility through controlled and patient samples, with benchmarking against FDA-approved assays. CPRIT support will enable Erisyon's scale-up and regulatory compliance activities, advancing toward FDA approval.

CPRIT funding will help Erisyon establish a high-impact diagnostic tool in Texas, supporting oncologists with improved patient stratification tools and furthering Texas's contributions to precision cancer diagnostics.

Select Reviewer Comments

"The applicants target a significant challenge in oncology: the early identification of non-small cell lung cancer (NSCLC) patients likely to benefit from checkpoint inhibitor therapy. … a newly developed test, in combination with the success of immune checkpoint inhibitors (ICIs), could benefit a substantial number of cancer patients."

"If successful, the project could significantly expand the eligible patient population for ICI therapy and aid in the development of more effective ICI therapies by offering accurate insights into tumor antigenicity."

"By specifically targeting the PSME4/PSMB10 ratio within tumor cells, this product directly indicates the tumor's status and its potential receptivity to ICI therapy, potentially overcoming a significant barrier in the current approach to cancer treatment."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Marker Therapeutics for $9,513,569.

No Contingencies

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.

Marker Therapeutics is advancing MT-601, a T cell therapy for metastatic pancreatic cancer (mPC), leveraging six tumor-associated antigens (mTAA) highly expressed in pancreatic cancer to reduce tumor escape and off-target effects. MT-601 is designed for outpatient administration, enhancing accessibility while minimizing toxicity, and has shown promising efficacy in lymphoma, with early pancreatic cancer trials indicating robust safety and initial efficacy.

MT-601's unique targeting mechanism allows it to recognize and kill tumor cells through native T cell receptors, addressing a critical need for more effective mPC treatments. Only 52% of patients are eligible for standard mPC chemotherapy due to high toxicity, making MT-601's non-toxic approach particularly valuable. The therapy's design avoids genetic engineering, providing a novel, safer immunotherapy alternative.

Marker's Phase 1 trial will assess MT-601 with FOLFIRINOX in mPC patients across multiple sites, including MD Anderson Cancer Center (MDACC). A dose-escalation phase and dose expansion cohort will evaluate safety and efficacy, with results supporting applications for Regenerative Medicine Advanced Therapy (RMAT) designation and facilitating progression to larger trials.

With CPRIT funding, Marker Therapeutics can advance MT-601 through clinical trials while expanding partnerships with Texas-based entities, supporting Texas's healthcare landscape with cutting-edge mPC treatments. The funding will expedite MT-601's path to market, offering new hope for patients with limited therapeutic options.

Select Reviewer Comments

"Given the unmet medical need of pancreatic cancer, the intended product will significantly address the treatment of this cancer."

"The company has obtained FDA orphan drug designation for MT-601 in treating metastatic pancreatic cancer, and preliminary clinical data show promising safety and efficacy."

"MT-601's target patient population, current clinical stage of development, excellent safety profile, potential for increased efficacy, and lack of genetic engineering gives MT-601 a considerable edge in the market."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Metaclipse Therapeutics for $6,080,245.

No Contingencies

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.

Metaclipse's Membrex vaccine, a personalized autologous immunotherapy, seeks to improve immune responses in head and neck squamous cell carcinoma (HNSCC) by overcoming resistance to immune checkpoint inhibitors (ICIs). Using tumor membrane vesicles (TMVs) from patient tumor tissue, Membrex combines tumor-specific antigens with potent immunostimulatory molecules to induce a more robust T-cell response.

Preclinical studies in HNSCC models have demonstrated Membrex's efficacy, showing increased T-cell infiltration, tumor growth reduction, and metastasis prevention. By sensitizing tumors to anti-PD-1 therapy, Membrex could extend the benefits of ICIs to a broader range of HNSCC patients who currently lack durable responses.

The Phase 1a/b clinical trial will assess Membrex's safety and efficacy in combination with ICIs, conducted at MDACC and additional Texas-based sites. GMP manufacturing will be supported by Texas-based CDMO Fujifilm Diosynth, ensuring operational continuity in the state.

CPRIT funding will enable Metaclipse to advance Membrex in Texas, establishing a base in Houston to drive clinical and operational growth. This support will boost Texas's role in personalized immunotherapy, advancing treatment options for HNSCC patients while fostering economic development.

Select Reviewer Comments

"Membrex vaccine immunotherapy has the potential to significantly address an unmet medical need in the treatment of recurrent HNSCC."

"The successful completion of the goals and objectives of this project will allow go / no-go decisions to be made about further clinical and product development, with strong potential for new drug products that can address current unmet medical needs."

"Membrex is poised to exercise one of many business strategies upon obtaining convincing clinical data in their Phase 2 study."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Barricade Therapeutics, Corp. for $14,005,034.65.

No Contingencies

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.

Barricade Therapeutics is developing TASIN-15, a novel therapy targeting the APC mutation (APCmut) prevalent in colorectal cancer (CRC), which is linked to cancer progression. TASIN-15 selectively inhibits Emopamil binding protein (EBP) with minimal off-target effects, offering a new therapeutic approach for advanced CRC patients.

With an 11% survival rate for metastatic CRC (mCRC), TASIN-15 presents a potential breakthrough by improving efficacy where standard therapies fall short. Preclinical studies show TASIN-15's favorable bioavailability, tissue penetration, and safety, paving the way for Phase 1 trials to establish dosage and efficacy.

Barricade seeks CPRIT funding to complete Phase 1 trials in advanced APCmut CRC patients, establishing TASIN-15's potential as a single-agent and combination therapy. The funding will also support Phase 1b expansion to assess broader therapeutic applications.

With CPRIT support, Barricade will demonstrate Texas's capacity for innovative cancer therapy, positioning TASIN-15 as a leading CRC treatment and strengthening Texas's biotech landscape through advanced clinical development.

Select Reviewer Comments

"Advanced colorectal cancer has a very poor 5-year survival rate. There are few effective, targeted treatments for these patients… A novel, targeted oral treatment would be a welcomed treatment option."

"If TASIN-15 is proven to be safe and effective in CRC, this new therapy would be an important step forward in treating this cancer."

"This therapeutic approach could offer a significant contribution to the management of colorectal cancer."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Orphagen for $10,213,909.

No Contingencies

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.

Orphagen Pharmaceuticals is developing OR-449, a small molecule antagonist targeting steroidogenic factor-1 (SF-1) for treating adrenocortical carcinoma (ACC). SF-1 is highly expressed in ACC and some head and neck and lung squamous carcinomas, with preclinical studies demonstrating OR-449's efficacy in inhibiting tumor growth.

OR-449 is designed to reduce reliance on existing ACC treatments, which have limited success rates. Preclinical toxicology studies have shown no adverse effects, supporting OR-449's advancement into clinical trials for ACC, where options are currently limited.

Orphagen's project aims to complete a Phase 1 clinical trial, exploring dosage and efficacy in adult and pediatric ACC patients. CPRIT funding will support site activation, interim analyses, and manufacturing necessary for the trial's success.

With CPRIT's support, Orphagen will establish its Texas presence, advancing OR-449 as a first-in-class ACC therapy and reinforcing Texas's role in developing rare cancer treatments.

Select Reviewer Comments

"ACC is a rare cancer with severe outcomes in later-stage disease. If this product proves effective, it could provide a significant improvement over the current standard of care for patients with advanced ACC who face limited treatment options."

"OR-449 is a first-in-class inhibitor of SF-1, a novel target for the treatment of ACC... If successful, this drug has the potential to be a breakthrough therapy for both pediatric and adult ACC patients."

"OR-449 has demonstrated considerable preclinical efficacy... The FDA's rare pediatric disease designation for OR-449 and feedback from the pre-IND meeting provide a positive regulatory pathway for advancing this promising candidate."

TTC

Curve assay against a gold standard (MRI), with results showing 95% sensitivity and 96% specificity."

"The market opportunity here appears strong, with a projected market size of over $10B in the U.S. for surveilling high-risk liver disease patients. Interviews with target physicians indicate that 92% are willing to order this new test if it can be reimbursed."

De-Identified Overall Evaluation Scores

Texas Diagnostic and Devices Company Awards

Product Development Research Cycle 25.1

Full Application Review

Application ID	Final Overall Evaluation Score
DP250157*	1.9
M	3.4
N	3.9
O	4.3
P	5.0

* Recommended for funding.

Texas Diagnostic and Devices Company Awards

Product Development Research Cycle 25.1

Final Scores for Preliminary Application Review

CPRIT uses a preliminary application review process to quickly provide an applicant with feedback about whether the proposed project is compatible with the CPRIT portfolio and mission. A panel of experts individually reviewed and scored preliminary applications using the criteria listed in the Request for Applications (RFA). These are the final overall evaluation scores for preliminary applications that were not invited to submit full applications. The review process ends after preliminary review for those applicants not invited to submit a full application.

Application ID	Final Overall Score
Ea	2.4
Eb	2.5
Ec	2.8
Ed	3.0
Ee	3.0
Ef	3.2
Eg	3.3
Eh	3.4

Final Overall Evaluation Scores and Rank Order Scores

October 29, 2024

Dr. David Cummings
CPRIT Oversight Committee Chair
Via email to dcummingsmd@yahoo.com

Ms. Kristen Pauling Doyle
CPRIT Program Integration Committee Chair
Via email to kdoyle@cprit.texas.gov

Dr. Cummings and Ms. Doyle,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 25.1 grant award cycle. The PDRC convened on October 28, 2024, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Curve Biosciences, Marker Therapeutics, Inc., Telos Biotechnology, Metaclipse Therapeutics Corp., Barricade Therapeutics, Corp., Ypsilon Therapeutics, Orphagen Pharmaceuticals, Inc., Eisbach Bio Inc., and Erisyon Inc. The attached table reflects the ranked award recommendation for the nine (9) grant applications. The recommendations contain no contingency.

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

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Council

CPRIT 25.1 Product Development Research
Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Application Title	Organization	Final Overall Score	Recommended Budget
1	DP250157	TDDC	New	Patnaik, R	Clinical Utility Study for the Commercial Launch of a Best-in-Class Liver Cancer Screening Blood Test for High-Risk Liver Disease Patients	Curve Biosciences	1.9	$ 12,600,000
2	DP250150	TTC	New	Vera, J	A Phase 1 Study of Multi-Tumor Associated Antigen Specific T Cells (MT-601) in Patients with Metastatic Pancreatic Cancer following frontline FOLFIRINOX	Marker Therapeutics, Inc.	2.1	$ 10,226,179
3	DP250143	SEED	Resubmission	Sayed, M	TELOVANCE: A Transient Telomere Lengthening Platform Designed to Enhance the Expansion and Efficacy of Human Cell and Gene Therapies	Telos Biotechnology	2.3	$ 2,998,945
4	DP250135	TTC	Resubmission	Pack, C	Personalized Immunotherapy for Recurrent, Resectable Head and Neck Cancer	Metaclipse Therapeutics Corporation	2.4	$ 6,395,245
5	DP250159	TTC	New	Thapar, N	(S)-TASIN-15 Phase 1 Dose Escalation, Optimization & RP2D Determination	Barricade Therapeutics, Corp.	2.4	$ 15,485,443
6	DP250137	SEED	New	Zha, D	Revolutionizing Solid Tumor Therapy with Bispecific TCRm Antibodies Targeting Intracellular Cancer Targets	Ypsilon Therapeutics	2.5	$ 2,997,500
7	DP250140	TTC	New	Thacher, S	A Phase 1 clinical trial of OR-449, a novel oral targeted therapy for pediatric and adult adrenocortical cancer patients	Orphagen Pharmaceuticals, Inc.	2.6	$ 10,917,769
8	DP250142	TTC	Resubmission	Schomburg, A	Eisbach Bio - Clinical Development of the ALC1 DDR inhibitor EIS-12656	Eisbach Bio Inc.	2.7	$ 5,000,000
9	DP250149	SEED	New	Swaminathan, J	Functional assay of immunoproteasome for patient stratification to checkpoint inhibitor therapy using single-molecule protein sequencing	Erisyon, INC	2.8	$ 2,242,852

Cancer Prevention & Research
Institute of Texas

CEO Affidavit
Supporting Information

Product Development Research
FY 2025—Cycle 1
Texas Therapeutics Company Awards

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA C-25.1-TTC

Texas Therapeutics Company Awards for Product Development Research

Please also refer to the Instructions for Applicants document

Preliminary Application Deadline: May 1, 2024

Full Application Invitation Issued: July 2024

Full Application Deadline: July 25, 2024

FY 2025

Fiscal Year Award Period

September 1, 2024-August 31, 2025

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RFA VERSION HISTORY

Rev	4/12/2024	RFA release

1. EXECUTIVE SUMMARY

Texas created the Cancer Prevention and Research Institute of Texas (CPRIT) to identify and financially support innovative projects related to the prevention, detection, and treatment of cancer. CPRIT's mission includes investing in Texas-based startup and early-stage oncology companies to narrow the funding gap (sometimes referred to as the "valley of death") between discovery and commercial development.

Texas-based companies and those companies willing to relocate to Texas may submit a preliminary application by the preliminary application deadline, which a panel of experts will review and score for scientific merit and consistency with CPRIT's portfolio. CPRIT will invite the best-scoring companies to submit a full application for review.

A company invited to submit a full application will present the proposed project to a panel of experts. If the panel recommends the company for potential CPRIT investment, the company will undergo due diligence before CPRIT makes a final award decision.

Applicants may request any amount of funding appropriate to the work proposed. Applicants should be cognizant, however, that CPRIT has limited funds for company investment (approximately $70 million per fiscal year). CPRIT will consider whether a project requesting a significant amount of funding is of such demonstrable importance in terms of innovation and impact that it should displace other worthy investments. Regardless of the amount requested, CPRIT will analyze and negotiate final budgets with grantees in an effort to fund as many worthy projects as possible.

CPRIT provides funding via an award contract between CPRIT and the company. The contract includes a negotiated budget tied to agreed goals and objectives (G&Os) and project timeline as well as revenue-sharing terms and regular reporting requirements on the use of CPRIT funds and project progress. CPRIT also requires companies receiving a Product Development Award to contribute the company's own funds toward the project contemporaneously with CPRIT's investment.

Please note that this RFA will use the terms "grant," "award," and "investment" interchangeably to denote the contractual commitment of CPRIT funds to support a company project recommended by an expert review panel and approved by CPRIT's Oversight Committee.

Commitment to Locating in Texas and Maintaining Business Presence in the State

Applying to this RFA indicates that the company will operate in Texas for the foreseeable future should it receive CPRIT funding. Do not apply if this is not your intention.

Texas taxpayer-supported general obligation bonds fund all Product Development Awards. Accordingly, in addition to scientific progress, CPRIT expects every company it funds to appreciably strengthen the Texas life science ecosystem through its presence in the state. A company receiving CPRIT funds must meaningfully commit to locating in Texas and maintaining its business presence within the state.

While CPRIT will work in partnership with your company to advance development of innovative treatments for cancer, we take your obligation to Texas seriously. Fraud, deception, or other actions taken in bad faith to evade the obligation to establish and maintain your status as a Texas company will result in termination, repayment, and any other remedy available by law or contract.

CPRIT developed criteria that CPRIT-funded companies should use to signal the company's commitment to Texas and to developing the state's life science ecosystem. Prior to submitting an application, applicants should familiarize themselves with the criteria specified in section 4.1 "Award Recipients Must Be Texas-Based, For-Profit Companies." If the company receives a CPRIT award, it must attest at least annually to fulfilling CPRIT's Texas location criteria.

2. ABOUT CPRIT

A statewide vote of Texans in 2007 created CPRIT and constitutionally authorized the state to issue $3 billion in taxpayer-backed general obligation bonds to fund cancer prevention and the research and development of innovative methods to prevent, detect, treat, and cure cancer. A second statewide vote in 2019 reauthorized CPRIT and increased the total general obligation bond issuance by another $3 billion, for a total of $6 billion.

2.1. CPRIT's Statutory Mission

The Texas Legislature has charged CPRIT with the following:

- Create and expedite innovation in 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.
- 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.

2.2. CPRIT's Product Development Research Program Priorities

In addition to overarching principles that include scientific excellence, impact on cancer, and increasing the state's life science infrastructure, CPRIT's Oversight Committee establishes annual priorities for each of its 3 programs. The priorities guide CPRIT in the development of RFAs and the evaluation of applications considered for awards.

The Product Development Research Program's priorities for FY25 are as follows:

- Funding novel projects that offer therapeutic or diagnostic benefits; 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 research entities
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level executives
- Providing appropriate return on Texas taxpayer investment

Information about CPRIT's program priorities is available at http://priorities.cprit.texas.gov/.

3. FUNDING INFORMATION AND MATCHING FUNDS REQUIREMENT

3.1. Overview

CPRIT provides project funding via a 3-year contract, with the opportunity to extend the contract duration based upon project progress. Funding is milestone driven, meaning that the company must fulfill the contractual G&Os associated with one funding tranche before receiving the next disbursement of funds.

3.2. Funding Stage for Texas Therapeutic Company Awards

Generally, at the time that an applicant applies to CPRIT pursuant to this RFA, the company has identified and characterized a lead compound; demonstrated efficacy in multiple translationally relevant animal models; completed pilot/dose-ranging toxicology studies; determined the feasibility of a scalable, GMP-compliant manufacturing process, including release assays; and identified a prototype formulation suitable for further development. The applicant is typically within 1 year from filing an IND or already in phase 1. Potential applicants that are not at or near this stage of product development should consider applying for a Texas Seed Company Award.

With appropriate justification, companies may use CPRIT funds to support the following:

- Studies that establish preclinical proof of safety and efficacy
- Chemistry, manufacturing, and controls (CMC)/manufacturing development
- GLP safety studies to support INDs
- Phase 1 studies in humans to establish safety and a recommended dose for phase 2
- Phase 2 studies to determine safety and efficacy in initial targeted patient population

CPRIT typically does not fund efforts outside of these parameters. Companies that have clinically demonstrated safety and efficacy should be able to acquire necessary capital via other sources; any request for later clinical trials must explicitly justify why CPRIT funding is appropriate. However, by exception, CPRIT may consider later-stage clinical trials projects where exceptional circumstances warrant investment.

3.3. Allowable Expenses

Companies may use CPRIT funds for expenses associated only with activities directly related to the specific project that CPRIT is funding. Allowable expenses include the following:

- 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
- Other appropriate research and development costs, subject to certain limitations set forth by Texas law

Texas Health & Safety Code Section 102.203 limits the amount of awarded funds that a company may spend on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

CPRIT's strong preference is to fund research and development rather than construction or facility renovation. Applicants intending to use any CPRIT funds for construction or facility renovation must offer extremely compelling circumstances justifying the request, ie, critical facilities that do not already exist in the state.

3.4. Required Matching Funds

CPRIT requires each company receiving a CPRIT Product Development Research Award to contribute funds under the company's control toward the overall project expenses. The company's expenditure of these "matching funds" must take place at the same time the company is drawing down CPRIT funds; there is no credit toward the matching funds requirement for in-kind expenses or expenditures made prior to the CPRIT award. The amount that the company will contribute toward the project is dependent on the total amount of CPRIT funds committed to the company.

The company must demonstrate that it has available matching funds at the time CPRIT disburses funds under the contract, not when the company submits the CPRIT application.

See section 9.3 for more information about CPRIT's matching funds requirement.

4. ELIGIBILITY AND RESUBMISSION POLICY

4.1. Award Recipients Must Be Texas-Based, For-Profit Companies

An applicant must be a Texas-based, for-profit company. An applicant may apply prior to company formation, but company formation must take place before award receipt. CPRIT will require the applicant to provide a data universal number system (DUNS) number before award receipt.

CPRIT considers a company to be Texas based if it fulfills at least 4 of the following criteria:

- The US headquarters are physically located in Texas.
- The chief executive officer resides in Texas.
- A majority of the company's personnel, including at least 2 other C-level employees (or equivalent), reside in Texas.
- Manufacturing activities take place in Texas.
- At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
- At least 1 clinical trial site is in Texas.
- The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

If appropriate, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

A company headquartered outside of Texas is eligible to apply for a CPRIT award, but the company must fulfill all location requirements identified in the application within 1 year of receiving the initial disbursement of CPRIT 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.

4.2. Contributors to CPRIT Ineligible to Receive CPRIT Awards

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 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.

4.3. Relatives of Oversight Committee Members Ineligible to Receive CPRIT Awards

An applicant is ineligible 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.

4.4. Debarment/Termination of a Federal Grant May Affect Eligibility to Receive CPRIT Awards

The applicant must report whether the company, company representative, or any other individual who contributes to the execution of the proposed project in a substantive, measurable way, regardless of whether the individual receives salary or compensation under the grant award, is ineligible to receive federal grant funds or has had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or any other individual is ineligible to receive federal grant funds or has had a grant terminated for cause, CPRIT will contact the applicant to provide more information to determine eligibility for CPRIT awards.

4.5. Only one Submission Per Applicant

Please note that in any given application round, applicants (a Company or PI) may apply for a single Product Development Award. Applicants should review each RFA and select the program that best fits their development status.

4.6. Resubmission Policy

A preliminary application previously submitted to CPRIT in the FY23 or FY24 review cycles but not recommended for funding may be resubmitted once and must follow all resubmission guidelines. CPRIT will not count against the resubmission limit an application previously

submitted in the FY23 or FY24 review cycles if CPRIT administratively withdrew the preliminary or full application without review.

CPRIT considers an application to be a resubmission if the proposed project is substantially 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 the company previously submitted to CPRIT does not constitute a new preliminary application for the purposes of CPRIT's resubmission policy. A change in the type of RFA such as changing from a Texas Therapeutic Company application to a Seed application may constitute a resubmission depending on the number and degree of changes from one application to the other. In such cases, the applicant should contact the program office prior to initiating the subsequent application (see section 10.2). CPRIT does not characterize an application as "submitted" for purposes of the resubmission policy if the applicant or CPRIT administratively withdrew the application prior to review.

5. APPLICATION REVIEW PROCESS AND CRITERIA

5.1. Overview

CPRIT uses a 3-step process to review company projects proposed for funding. The steps include (1) preliminary application, (2) full application and interview, and (3) due diligence review. An integrated panel of individuals with expertise in a wide variety of scientific fields including oncology as well as experts with experience in bringing products to market and those familiar with regulatory approval processes will review the applications. Cancer patient advocates also participate in the review of full applications.

Initially, applicants must submit a preliminary application. Based primarily upon a review of the scientific merit of the project as described in the preliminary application, CPRIT may invite a company to submit a full application and interview. The review of full applications will consider the quality of the research project and management team, commercial viability, product feasibility, scientific merit, project budget, timeline and goals, the potential suggested by preclinical results, and the opportunity to address unmet medical need. If the review panel is favorably inclined to recommend the full application for funding after the interview, the application will undergo a due diligence review by the panel as well as by third-party reviewers,

such as IP counsel. The due diligence review is intended to identify red flags that may negatively impact the panel's final recommendation regarding funding.

CPRIT conducts all stages of the review in confidence to protect the applicant's technological, scientific, and proprietary information. Individuals involved in the review process operate under strict conflict-of-interest prohibitions and nondisclosure agreements. Applicants must not contact or discuss a pending application with anyone involved in making a final decision on the application unless specifically invited by CPRIT to provide information on the proposed project.

CPRIT makes funding decisions via the review process and review criteria described below. CPRIT's Administrative Rules, Chapter 703, Sections 703.6 to 703.8 delineate the review process in more detail.

5.2. Review Process – Preliminary Applications

CPRIT uses a preliminary review process to quickly provide an applicant with feedback about whether the proposed project is compatible with the CPRIT portfolio and mission.

Preliminary applications must be submitted by May 1, 2024, 4 PM central time. A panel of experts will individually review and score the preliminary application using the criteria listed below. The panel reviewers may meet collectively to discuss the final decision regarding the preliminary application and will decide whether to invite the applicant to submit a full application for award consideration. In early July 2024, CPRIT will issue invitations to submit full applications to companies with the best-ranking preliminary application scores. The review process ends after preliminary review for those applicants not invited to submit a full application.

5.3. Review Criteria – Preliminary Applications

The review panel will evaluate the preliminary applications based on the scientific merit of the technology underlying the proposed project and whether the company presents a compelling idea for CPRIT investment.

5.4. Review Process – Full Applications

5.4.1. Product Development and Scientific Review

CPRIT assigns full applications to individual CPRIT product development review panel members for evaluation using the criteria listed in section 5.5. In addition to reviewing the

written application, the review panel will provide questions to the company that the company will address during a meeting convened virtually for the applicant to present the application in person. Importantly, the applicant should provide CPRIT with any correspondence that the company has conducted with regulatory agencies (eg, the FDA) in section 8.8.10 of the application and also promptly submit any new correspondence that occurs at any time during the course of the review.

5.4.2. Due Diligence Review

Following the in-person presentations, a subset of applications that the review panel judges to be most meritorious will move forward for additional in-depth due diligence, including, but not limited to, IP, management team strength, regulatory considerations, manufacturability, and market assessments.

After the due diligence review, the review panel will determine whether to recommend the application for a CPRIT award. The Product Development Review Council will create a final ranked list of applications recommended for funding by the review panels. The Product Development Review Council's ranking will be based on scores and programmatic priorities.

5.4.3. Program Integration Committee (PIC) Review

The CPRIT Program Integration Committee (PIC) meets to review the Product Development Review Council's final list of applications recommended for funding. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding when creating its comprehensive list of award recommendations for the Oversight Committee. By law, the PIC's list of recommended Product Development Awards may not include any applications not also recommended by the Product Development Review Council.

5.4.4. Oversight Committee Approval

CPRIT's Chief Product Development Officer will present the PIC's award recommendations at a public meeting of the Oversight Committee for approval by two-thirds of the Oversight Committee members present and eligible to vote. By law, the Oversight Committee may not approve any Product Development Awards to applicants not also recommended by the Product Development Review Council and the PIC.

5.5. Review Criteria – Full Application

Generally, the review panel will assess an application on the scientific merit, the quality of the company and management team, the appropriateness of the proposed project, and the potential clinical impact. A successful applicant's proposal will have no significant weaknesses in any of the following areas:

- Unmet medical need
- Potential clinical impact
- Relevant proof-of-concept studies (including preclinical safety/efficacy studies) and, where relevant, target validity studies supporting expectations of clinical impact
- Proposed integrated product development plan (IPDP)
- Communications with regulatory agencies
- Present and anticipated competitive landscape, together with justification for assumptions of competitive advantages of product in question
- IP
- Business/commercialization prospects
- Relevant experience and accomplishments of management team and key consultants
- Adequate budget and project timeline paired with realistic G&Os
- Overall commitment to Texas

See the appendix for more information on review criteria.

5.6. Confidential, Conflict-Free Review

CPRIT conducts each stage of application review confidentially and requires all CPRIT Product Development Review Panel members, Product Development Review Council members, PIC members, Oversight Committee members, and CPRIT employees with access to grant application information to sign nondisclosure statements regarding the contents of the applications. State law (Texas Health & Safety Code §102.262[b]) protects all technological and scientific information included in the application from public disclosure.

CPRIT will notify an applicant regarding the peer review panel assigned to review the grant application. CPRIT lists the review panel members on our 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.

5.7. Reconsideration of an Application Review Decision Limited to Unreported Conflicts of Interest

CPRIT is committed to providing a fair, unbiased review process conducted by expert reviewers familiar with the science, development stage, and business challenges underlying the project proposed for funding. That said, application review is a subjective process. **By applying, the applicant agrees and accepts that the sole basis for reconsideration of an application is a reviewer's undisclosed conflict of interest as set forth in CPRIT Administrative Rule 703.9.**

5.8. Prohibited Communication Between Applicant and Reviewers During Review

Except as noted below, CPRIT prohibits communication regarding any aspect of a pending preliminary or full application 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. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

- The communication prohibition begins at the time the applicant submits the preliminary or full application and extends until it receives notice regarding a final decision on the application. An applicant invited to submit a full application who has questions about the application process or the substance of the application should contact the CPRIT Product Development Program Manager.
- The communication prohibition does not apply when CPRIT staff or reviewers specifically invite the applicant to discuss the pending application for purposes of the review process, such as the in-person presentation or to respond to information requests during due diligence review. CPRIT will document communication between the applicant and CPRIT staff/reviewers, including the reason for the communication, as part of the grant review process records.

NOTE: The following individuals are members of the PIC: 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.

6. SUBMISSION GUIDELINES AND DEADLINES

By submitting an application, the applicant accepts the terms and conditions of the RFA.

Carefully review information in this section and the *Instructions for Applicants* document to ensure the accurate and complete submission of all components of the application. It is imperative that applicants allow sufficient time to familiarize themselves with the application format and instructions to avoid unexpected issues. CPRIT will administratively withdraw without review any application that lacks 1 or more required components, exceeds the specified page or word limits, or fails to meet the eligibility requirements listed in section 4.

6.1. Online Application Receipt System

Applicants submit preliminary and full applications via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal are eligible for evaluation.** To create and submit an application, there must be a named Principal Investigator (PI) and a named Application/Authorized Signing Official (ASO) who both have CARS user accounts. NOTE: An application cannot be submitted without ASO approval. The same person may serve as both the PI and the ASO; however, a separate account (with separate username and password) must be set up for each role. The *Instructions for Applicants* document associated with this RFA provides information about establishing a user account.

6.2. Invitations to Submit Full Applications Valid Only for the FY25 Review Process

The invitation to submit a full application is valid only for the current FY25 review cycle. An applicant who is invited to submit a full application for the first FY25 review cycle but does not do so must restart the review process by resubmitting the preliminary application in a future review cycle.

6.3. Preliminary and Full Application Submission Deadlines; Other Key Dates

Preliminary Applications: An applicant may submit a preliminary application via CARS by May 1, 2024, 4 PM central time. Following the review and scoring of all preliminary applications, CPRIT will issue a limited number of invitations to submit a full application in early July 2024 to the companies with the best-ranking scores.

Full Applications: CPRIT will convene panels for review of full applications submitted by the July 25, 2024, deadline. Key dates for the current FY25 review cycle are as follows:

FY25 Review Cycle 1

Full Application Deadline	July 25, 2024, 4 PM central time
In-Person Presentation	September 2024
Due Diligence	September-October 2024
Oversight Committee Meeting	November 20, 2024

6.4. Submission Deadline Extensions

Review cycle schedules are set in advance and do not accommodate receipt of a preliminary or full application days after the deadline. Therefore, potential applicants that are unable to meet the application deadline because of travel, sabbaticals, conferences, prolonged illness, or other leave, etc, should not request additional time to file an application but should instead consider applying in the next review cycle.

In exceptional instances, CPRIT may extend the submission deadline for a preliminary or full application upon a showing of good cause, usually for technology problems related to CARS. In this event, the applicant should submit a request to extend the submission deadline via email to the CPRIT Helpdesk within 8 hours of the submission deadline. If CPRIT approves the applicant's request for extension, then CPRIT will reopen CARS for a 2-hour window to allow an applicant with an unsubmitted application to complete and submit it. CPRIT will document submission deadline extensions, including the reason for the extension, as part of the grant review process records.

CPRIT urges applicants to initiate the registration process in CARS several business days prior to deadline to ensure enough time to complete and apply. The applicant's failure to adequately

review application instructions and plan accordingly to avoid unexpected issues is not sufficient grounds to justify approval for a late submission.

6.5. Product Development Review Fee for Full Applications

All applicants submitting a full application must pay a nonrefundable fee of $1,000 to partially offset the cost of reviewing Product Development Award applications. The application review fee must be postmarked by the full application submission deadline unless CPRIT approves a request to submit the fee after the deadline. Applicants should only submit an application fee after an official invitation to submit a full application has been issued from CPRIT.

Applicants should make the payment by check or money order payable to "Cancer Prevention and Research Institute of Texas." On the check or money order, please indicate the full grant application ID and the name of the applicant (PI) of the application. CPRIT cannot accept electronic or credit card payments.

Applicants using the US Postal Service to mail the application review fee should send it to CPRIT's PO Box (see address below.) **DO NOT** use CPRIT's physical address when mailing checks via the US Postal Service.

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

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

For those applicants using a delivery service (eg, FedEx, UPS) to send the application review fee, CPRIT's physical address is as follows:

Cancer Prevention and Research Institute of Texas
Wm B Travis State Office Building
1701 N Congress Ave Ste 6-127
Austin, TX 78701

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

7. PRELIMINARY APPLICATION COMPONENTS

CPRIT strongly advises applicants to attend the webinar offered by CPRIT before applying (https://cprit.texas.gov/news-events/webinars/).

7.1. Abstract (maximum 1,500 characters)

Explain the question or problem to be addressed and the approach to its answer or solution. The aims of the application should 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 an impact on cancer. Describe the unmet medical need addressed by the proposed project. Briefly explain the product, service, technology, or infrastructure proposed and funding needs. Note that the character limit includes spaces.

7.2. Executive Summary (maximum 2 pages)

The Executive Summary should demonstrate the applicant's ability to think strategically and to orchestrate the execution of key operational aspects of cancer drug development. Listed below are some key elements to address in the Executive Summary. CPRIT encourages applicants to provide concise responses in bulleted format.

a. Company location and year of incorporation
b. Brief description of asset/technology
c. Target/mechanism of action
d. Initial target indication(s)/patient populations: tumor type(s), stage, extent of prior standard-of-care (SOC) therapy
e. Unmet medical need of initial target indications
f. Target validation, for example, via knockdown studies; pharmacological intervention; clinical/epidemiological target correlations with stage of disease/prognosis; selectivity of target expression: malignant vs normal cells
g. Characteristics of agent/target interaction: potency, reversibility, selectivity, pharmacodynamic (PD) effects
h. In vitro preclinical efficacy characterization (eg, cell lines tested with corresponding EC50s selectivity vs normal cells; potency vs competitive agents)

i. In vivo preclinical efficacy characterization (list animal models tested; potency vs SOC; tumor growth inhibition vs tumor regression; effects on survival; combination studies)
j. In vivo tumor data supporting in vivo proof of concept
k. Absorption, distribution, metabolism, and excretion (ADME), pharmacokinetics (PK), toxicokinetics (TK) (brief statement addressing status of key studies and results if available)
l. Safety characterization to date
m. Biomarker candidates, if any, for companion diagnostic test development
n. Manufacturing/CMC development status
o. Clinical trial status and plans forward to be covered by the grant
p. Regulatory status and plan (eg, brief summary of agency interactions to date, **including any communications with a regulatory agency, US or foreign,** and planned, likely regulatory paths)
q. High-level overview of work to be done during the grant, including key milestones and budget estimates by year; manufacturing/CMC; safety toxicology; further in vivo efficacy characterization; biomarker exploration; diagnostic test development; clinical plans
r. Potential competitive advantages together with supporting rationale
s. Senior management team accomplishments in cancer drug development
t. Company financial status/fundraising plans
u. Commitment to Texas

7.3. Slide Presentation (maximum 16 slides)

Provide a slide presentation summarizing the proposed project, scientific support, and management team. The slides should succinctly capture all essential elements of the proposed project and should be sufficiently encompassing to be a standalone document. Submit the presentation in PDF format, with 1 slide filling each landscape-orientated page.

7.4. Proposed Project Aims and Budget (maximum 1 page)

Succinctly describe the aims of the proposed project. Provide an anticipated budget request for the project, linking the aims to expected budget amounts. Should CPRIT invite the applicant to submit a full application, the proposed aims and budget will serve as the basis for the project G&Os and requested budget.

7.5. Resubmission Summary (maximum 1 page)

If the applicant submitted a preliminary or full application to CPRIT in previous fiscal years, upload a brief summary of the revised approach, including a summary of the applicant's response to specific feedback. The Resubmission Summary is distinct from the Executive Summary. Clearly indicate to reviewers how the applicant has improved the proposal in response to the critiques from CPRIT. In the Resubmission Summary, refer to specific sections in the resubmission where the reviewer may find further detail on the questions and feedback to the original application.

Responsiveness to previous critiques is a factor in the review. However, reviewers will assess and score the resubmission as a whole, not solely based on improvement and progress made. The review panel for the resubmission may differ from the previous review panel.

8. FULL APPLICATION COMPONENTS

CPRIT does not require or request letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc. Do not submit letters of support as part of your preliminary or full application package. CPRIT will remove any such information from your application before review. Applicants should minimize repetition among application components to the extent possible and use discretion when cross-referencing sections to maximize the amount of information presented within the page limits. Note that where character limits are specified, spaces are included in the character limit.

8.1. Abstract and Significance (maximum 5,000 characters)

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.

8.2. Layperson's Summary (maximum 1,500 characters)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Explain how the proposed project supports CPRIT's statutory mission. For example, will the project fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Will it synergize with Texas-based resources? Address how the company's work, if successful, may have a major impact on the care of patients with cancer.

Do not include any proprietary information in this section because CPRIT makes the Layperson's Summary publicly available (eg, posted on CPRIT's public website) if the company receives CPRIT funding.

Advocate reviewers use the Layperson's Summary when evaluating the significance and impact of the proposed work.

The Layperson Summary should describe the following:

a. How the proposed project specifically supports CPRIT's mission
b. The overall goals of the work
c. The type(s) of cancer addressed
d. The potential significance of the results
e. The impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer
f. How the company's work, if successful, may have a major impact on the care of patients with cancer

8.3. Goals and Objectives (G&Os) (maximum of 1,200 characters each)

List specific G&Os for each year of the project. G&Os should be clearly delineated, realistic, and consistent with the IPDP and timeline to allow for unambiguous measurement of progress. While the G&Os may be more detailed than the proposed project aims included in the applicant's preliminary application, the G&Os should not vary significantly from the proposed project aims.

The G&Os are a fundamental aspect of the application; applicants should carefully consider and justify each proposed G&O. CPRIT will incorporate the G&Os into the award contract and will use the G&Os to evaluate progress of the funded project. Demonstrating the timely and successful achievement of G&Os is necessary before CPRIT will advance the next tranche of funding. While it is laudable to pursue aggressive goals, failure to achieve a goal or objective during the specified time will result in CPRIT withholding funds until the company can show that the company has completed the outstanding issue.

NOTE: CPRIT and the company may negotiate a contractual change to 1 or more G&Os during the funded project as scientific progress and development activities dictate; however, material changes will require substantial justification because the G&Os are part of the foundation of the funding decision by CPRIT.

8.4. Executive Summary (maximum 2 pages)

The Executive Summary should demonstrate the applicant's ability both to think strategically and to orchestrate the execution of key operational aspects of cancer drug development. Listed below are some key elements to address in the Executive Summary. CPRIT encourages applicants to provide concise responses in bulleted format. NOTE: The applicant may submit the same Executive Summary it provided in its preliminary application or may update it, as necessary.

a. Company location and year of incorporation
b. Brief description of asset/technology
c. Target/mechanism of action
d. Initial target indication(s)/patient populations: tumor type(s), stage, extent of prior SOC therapy
e. Unmet medical need of initial target indications
f. Target validation, for example, via knockdown studies; pharmacological intervention; clinical/epidemiological target correlations with stage of disease/prognosis; selectivity of target expression: malignant vs normal cells
g. Characteristics of agent/target interaction: potency, reversibility, selectivity, PD effects
h. In vitro preclinical efficacy characterization (eg, cell lines tested with corresponding EC50s selectivity vs normal cells; potency vs competitive agents)

i. In vivo preclinical efficacy characterization (list animal models tested; potency vs SOC; tumor growth inhibition vs tumor regression; effects on survival; combination studies)
j. In vivo tumor data supporting in vivo proof of concept
k. ADME, PK, TK (brief statement addressing status of key studies and results if available)
l. Safety characterization to date
m. Biomarker candidates, if any, for companion diagnostic test development
n. Manufacturing/CMC development status
o. Clinical trial status and plans forward to be covered by the grant
p. Regulatory status and plan (eg, brief summary of agency interactions to date, **including any communications with a regulatory agency, US or foreign,** and planned, likely regulatory paths)
q. High-level overview of work to done during the grant, including key milestones and budget estimates by year; manufacturing/CMC; safety toxicology; further in vivo efficacy characterization; biomarker exploration; diagnostic test development; clinical plans
r. Potential competitive advantages together with supporting rationale
s. Senior management team accomplishments in cancer drug development
t. Company financial status/fundraising plans
u. Commitment to Texas

8.5. Timeline (maximum 1 page)

Provide a visual depiction of anticipated major milestones 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. CPRIT will include the timeline in the executed contract. An applicant should avoid including information that it considers confidential or proprietary in this section.

If the IPDP (see section 8.8) incorporates or depends on results from parallel studies or development programs that CPRIT is not funding, the Gantt chart/timeline should reference these studies, their timelines, and the contingencies they create or resolve with the studies and G&Os funded by CPRIT.

CPRIT will review timelines for reasonableness. Applicants should provide realistic timelines because the G&Os link directly to the timeline. If CPRIT approves the application for funding,

the award contract will include the approved timeline. Adherence to timelines is a criterion for continued support of successful applications.

8.6. Slide Presentation (maximum 10 slides)

Provide a slide presentation summarizing the application. Submit the presentation in PDF format, with 1 slide filling each landscape-orientated page. The slides should succinctly capture all essential elements of the application and should be sufficiently encompassing to be a standalone document.

8.7. Resubmission Summary (maximum 2 pages)

If the applicant submitted a preliminary or full application to CPRIT in previous fiscal years, upload a summary of the revised approach, including a summary of the applicant's response to specific feedback. The Resubmission Summary is distinct from the Executive Summary. Clearly indicate to reviewers how the applicant has improved the proposal in response to the critiques from CPRIT. In the Resubmission Summary, refer to specific sections in the resubmission where the reviewer may find further detail on the questions and feedback to the original application.

Responsiveness to previous critiques is a factor in the review. However, reviewers will assess and score the resubmission as a whole, not solely based on improvement and progress made. The review panel for the resubmission may differ from the previous review panel.

8.8. Integrated Product Development Plan (IPDP) (maximum 12 pages)

8.8.1. Overview

An IPDP consists of the following:

a. The preclinical development plan describing the studies required to generate safety data to support clinical development
b. The clinical development plan that provides the necessary safety and efficacy data supporting marketing approval
c. The CMC plan to ensure that the company has sufficient investigational product available for both sets of studies
d. The regulatory activities and timelines associated with each plan
e. Copies of all communications with any regulatory agency, US or foreign

The IPDP should be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, data should drive the IPDP.

Applicants may provide references for the IPDP section as a standalone document that the applicant will separately upload into CARS. In the interest of brevity, include only the most pertinent and current literature. While references will not count toward the IPDP section page limit, it is essential to be concise and to select only those references relevant to the IPDP. Do not use the references to circumvent IPDP section page limits by including data analysis or other nonbibliographic material.

This section highlights components of the IPDP that are of fundamental importance during the peer review and scoring process. Please note that this may not be all inclusive. When addressing future work, use the appropriate sections below as guidance. CPRIT recognizes that applications addressing early-stage research may not have information for all sections.

8.8.2. Target Product Profile (TPP)

A target product profile (TPP) that projects a clear path to full commercialization is essential to a solid IPDP. The TPP serves as a summary of the product development program described in terms of a marketed label with supporting data. It includes information on conducted and planned studies and serves to facilitate the company's interactions with regulatory authorities. The comprehensive TPP may also include commercial information, IP positions, and ultimately go/no-go decision criteria to determine whether a product development program should proceed or end.

Because the TPP is an abstract of the IPDP, CPRIT encourages the applicant to complete the TPP prior to drafting the IPDP. The applicant may employ a basic or comprehensive approach to the TPP.

Many companies use the US Prescribing Information format to create the TPP:

https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources. The applicant may also use the European Union (EU) Summary of Product Characteristics format:

https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/how-prepare-review-summary-product-characteristics

CPRIT considers the following topics appropriate for a comprehensive TPP:

a. Therapeutic modality: small molecule, biologic, special formulation (eg, liposome encapsulation), etc.
b. Therapeutic objective: treatment, prevention, supportive care, eg, adverse event (AE) prevention/amelioration
c. Target and target validity
d. Mode of action and how demonstrated in tumor cells: (1) in vitro; (2) in vivo
e. Initial indication(s)/patient population(s), including their selection based upon genomic characteristics (with the potential need for a companion diagnostic device):
    1) Tumor type, stage, line of therapy/resistance to SOC, patients selected by biomarker expression
    2) Preclinical evidence for the intended target being engaged, antitumor effectiveness in translationally relevant models, ie, corresponding to target patient population(s)
f. Potential follow-on indications (as above)
g. Dosage form/drug product: stability; storage conditions; if applicable, reconstitution aspects
h. Administration: Monotherapy
    1) Projected dose
    2) Route
    3) Regimen
    4) Duration: describe preclinical safety studies supporting duration of administration
    5) Food effect studies, if any
    6) Need, if any, for coadministration of AE prophylactic medications
i. Administration: Combination regimens
    1) Anticipated safety profile
    2) Compatibility of administration schedule with that of combination agent(s)
j. Target clinical efficacy:
    1) Specify efficacy end points, target effect sizes, and if applicable, duration of effect. In the case of overall survival/progression-free survival end points, specify target hazard ratios and type of control.

2) Describe clinical trial designs intended to demonstrate these effects: single arm/randomized, trial end points, sample size/statistical aspects.

k. Target safety profile

1) Adverse events anticipated from preclinical safety studies

2) Preclinical safety studies ruling out certain AEs (eg, CEREP screening, CYP isoform studies, hERG; cardiac, renal, liver AEs; immunogenicity).

3) Anticipated contraindications if any

4) PK properties

5) ADME features

l. Features of the product providing a competitive advantage to relevant SOC (specify)

m. IP protection

1) Type of claims (composition of matter, formulation, methods, use)

2) Patent expiry in major jurisdictions

3) Freedom to operate

n. Target cost of goods (COGs)

8.8.3. Target Validation

If this is a targeted agent, describe the extent to which the company has validated the target (eg, through knockdown studies and/or pharmacological intervention), including, but not limited to, the following:

a. Demonstration of engagement of the target with the agent by biochemical assay including the potency of the agent, binding characteristics, affinity vs natural ligand, reversibility.

b. In vitro evidence showing downstream PD markers of target modulation.

c. Demonstration that the agent has biologically significant modulation of the target in vivo.

d. In vivo studies exploring PK/PD in the periphery and in tumor tissue, together with demonstration of target engagement/target exposure and modulation in tumor tissue.

e. Describe whether the target is uniquely or substantially overexpressed by tumor versus normal cells and its frequency, by tumor expression level, in target patient population(s). If available, describe the prognostic significance/clinical outcome correlates of target expression in patients with cancer.

f. If the target represents an activating mutation, characterize binding of the agent to the target and other activating mutations.
g. If available, describe any externally/independently confirmed demonstration of the company's target validation studies.
h. Describe any known mechanisms of resistance to the modulation of this target and possible mitigation/preemptive approaches, such as combination therapies.

8.8.4. Lead Optimization

For small molecules:

a. Is there scope for further lead optimization through structure-activity studies?
b. Describe lead optimization criteria, process, and lead characteristics/properties.
c. 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?
d. In the case of agents intended for oral absorption, are there any issues with water solubility? Do formulation and stability studies indicate the feasibility of oral administration?
e. Summarize formulation development efforts to date, including for parenteral administration if relevant.
f. Outline synthesis and process development work to date. Yields? Commercial feasibility? Identify essential vendors and backup plans in case of supply chain challenges.
g. Describe stability characteristics of the drug substance and the drug product.

For biologics:

a. Describe the status of cell line/master cell bank development and characterization.
b. Describe the purification process and likely scalability.
c. Describe status of manufacturing upstream and downstream scaleup and any special scaleup challenges anticipated that would significantly impact COG.
d. Describe results of physical and biological stability studies carried out on the lead protein.

e. If applicable, describe status of formulation (drug product) development and status of stability studies. Has the absence of aggregation been demonstrated with (1) the drug substance and (2) the drug product?
f. Overall status of assay development/manufacturing including bioanalytical processes for product release and for stability studies
g. Identify essential vendors and backup plans in case of supply chain challenges.

8.8.5. Preclinical Characterization: Safety

Any pharmaceutical product must undergo a thorough safety evaluation prior to commencing human studies, including non-GLP and GLP animal safety and toxicology studies. CPRIT strongly advises the applicant to seek input directly from regulatory guidelines (eg, FDA, EMA [EU], TGA [AU], etc) for safety studies for small molecules and biologicals and to seek PK/PD and toxicology expertise by hire, contract, or consulting agreement with subject matter experts with demonstrated and successful track records in this field.

When providing information for the safety section, consider the following guidelines and prompts listed below. The extent and type of information provided in the safety section is largely dependent on the type and the stage of the intended product (ie, pre-IND stage, IND enabling, IND filing).

NOTE: As set forth in section 8.8.10, the applicant must provide any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application.

a. Overall, defend the results of safety characterization suggesting that the agent is reasonably derisked from a safety perspective. If the extent of preclinical safety characterization is insufficient to address this question now, explain the planned safety studies that will address this issue.
b. Describe, considering potency and target selectivity, what the potential is for both off-target and pharmacologically on-target deleterious effects.
c. Justify selection of drug concentrations and confirm that exposures are associated with substantial antitumor efficacy/PD effects and can be achieved safely in vivo. Also ensure that an appropriate drug concentration range is included for repeat-dose toxicology

studies. Ultimately, the goal is to establish a therapeutic index and give guidance to the determination of a first-in-human dose.

d. Indicate the form of the product used in the toxicology studies or how the study will be carried out (eg, research form, manufacturing process completed, drug substance, formulated drug product).

e. Summarize findings from general toxicology studies (non-GLP and GLP if available). When providing the results, include the species tested and explain the rationale for their use; the numbers of animals/group; the route(s) of administration; dose schedules, etc. If there is concern for safety involving a particular organ system, report the histopathology results if complete.

f. Describe methodology/results of PK and TK studies. Are there safety concerns related to (lack of) dose proportionality, interanimal variability/outliers/accumulation? Are there any issues with the distribution or metabolism of the agent?

   For small molecules, the applicant should include the following information under a separate subheading:

   - ADME characterization
   - Genotoxicity studies
     - Mutagenicity: Evaluation of DNA damage by subjecting the drug to several bacterial strains.
     - Clastogenicity: Evaluation of chromosomal damage
   - Data from CEREP type screening, CYP 450, and hERG/ion channel interactions

   For biologics, the applicant should include the following information under a separate subheading and describe the methodology underpinning these studies:

   - General toxicology in monkeys or relevant nonhuman primate
   - Immunogenicity testing for monoclonal antibodies

g. If safety is conditional on multimodal response in a combined therapy (eg, synergies between separate immune system modulation and direct tumor cell effects), indicate the rationale for the in vitro and in vivo studies and the performance criteria selected to be predictive of the safety in humans.

8.8.6. Preclinical Characterization: Efficacy

For applications with projects at the preclinical stage, this section is the most critical element for reviewers to assess the robustness of preclinical efficacy characterization and the justification for the applicant's expectations for clinical efficacy.

In vitro studies

a. List tumor cell lines, describing study methodology and results (EC50s); feasibility of safely achieving in vivo/systemic concentrations associated with antitumor activity in vitro.
b. If the applicant intends to use the agent as part of a combination regimen for initial target indications, describe methodology/results of combination studies seeking to demonstrate additivity/synergy.

In vivo studies

a. Describe tumor models and their translational relevance to initial indications/patient populations (extent of disease, prior exposure/resistance to SOC agents); patient-derived xenograft (PDX) models are strongly preferred and if not used, provide justification why they cannot be used. Investigational agent should be dosed preferably via the intended clinical route of administration.
b. Describe study designs/methodology. This may include, but is not limited to, sample size per arm; comparisons, if any, with optimally dosed SOC agents; extent (for example tumor volume in mm^3) to which tumors were established at the time of treatment initiation, duration of follow-up.
c. When describing results, include if applicable, in vivo drug tumor concentrations, achieved tumor PD effects/evidence for target modulation/inhibition of target in tumor tissue, effects on tumor progression, tumor growth inhibition vs tumor regression, rate and duration of complete tumor regressions, effects on overall survival vs inactive/active controls, as applicable.
d. If the applicant intends to use the agent in combination therapy for initial target indications, describe methodology/results of combination studies seeking to demonstrate additivity/synergy; briefly indicate whether the applicant plans additional in vivo efficacy characterization for inclusion in the IND. It is also advisable to determine potential toxic

effects of the combination, including SOC. If such efficacy is conditional on multimodal response (eg, synergies between separate immune system modulation and direct tumor cell effects), define how the applicant will choose in vitro and in vivo studies and the performance criteria selected to be predictive of efficacy of such synergy in humans.

e. Is there independent confirmation of critical antitumor proof-of-concept studies?

8.8.7. Clinical Study Development Plan

If the company proposes to carry out clinical studies with CPRIT funds, indicate the study phase (eg, phase 1a, phase 1b/2, phase 2) and the primary and secondary objectives including any key safety assessments/end points and additional assessments (eg, PKs, PDs, other, as applicable).

NOTE: As set forth in section 8.8.10, the applicant must provide any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application.

Describe the study design, including the following information:

a. Patient population, including the case and control groups (if applicable). The applicant should document the inclusion and exclusion criteria for the trial, explain the appropriateness of patient populations from a safety perspective, and justify the generalizability of results to target product profile patient population.
b. Randomization scheme and/or comparator/control arm. In the case of controls, justify the choice of control.
c. Justification for clinical trial sample size including statistical considerations.
d. Justification of target efficacy effect size if applicable, eg, if the company intends the study to support accelerated approval, general approval, or inform go/no-go decision-making.
e. Discuss clinical relevance of target effect size.
f. Adaptive study designs (Bayesian or frequentist) should be clear on design criteria and clinical rationale. For sequential designs with interim analyses, define the impact on design criteria and power. Also define relevant stopping rules and related justification of expected clinical performance criteria.

g. Drug administration information that details the route, frequency, and duration of treatment, and whether the agent will be given as a monotherapy or combination. If combination, discuss acquisition costs/access to combination agent.
h. Study implementation information describing the number of investigational sites and the estimated patients enrolled per site. Explain whether the site has competing study protocols and how this will impact accrual. Describe the incidence/numbers of patients meeting patient population description per site. Discuss initiatives the company plans to address recruitment challenges. Detail the study activities that the company will contract out vs activities it will manage internally. Demonstrate that relevant clinical operations experience is present within the study team.
i. Study timeline, including key startup activities (see below).
j. Study budget broken down by major cost/driver areas and a fully inclusive figure representing the total study budget.
k. Describe the extent of contract research organization (CRO) input into budget preparation and include any quotations/estimates from any CROs or other third parties providing clinical trial services in the Budget Justification (see section 8.12).

8.8.8. Pharmaceutical Properties/Chemistry, Manufacturing, and Controls (CMC)

The quality of drug substance and drug product is determined by their design, development, in-process controls, GMP controls, process validation, and specifications applied to them throughout development and manufacture. An applicant should ensure that they have sufficient expertise and resources to address these activities in the preparation of the documentation required for their IND submission and eventually their NDA/BLA.

CPRIT advises applicants to seek expert input for the performance of the CMC-related activities and for the preparation of the CMC section of their proposals to appropriately project cost, efforts, and timelines for the manufacture of the investigational product for all stages of clinical and nonclinical development. The applicant should refer to the International Conference on Harmonization Quality Guidelines located at https://www.ich.org/page/quality-guidelines.

NOTE: As set forth in section 8.8.10, the applicant must provide any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions

with regulatory authorities (such as FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application.

8.8.9. Regulatory Plan

Regulatory input on the company's TPP is critical to finalize the IND-enabling, clinical, nonclinical, and CMC activities that define the IPDP. While companies may plan an exit strategy prior to bringing a product to late-stage clinical development (P2 and or P3) or to the market, the development and adherence to a logical, expeditious, and fully integrated regulatory plan is advisable to maximize value for any potential purchaser.

Accordingly, the Regulatory Plan is an important part of the CPRIT application and an opportunity for the successful applicant to demonstrate proficiency and expertise. In detailing the proposed regulatory plan, the applicant should address the considerations and topics listed below.

a. Identify the point of contact with regulatory authorities. The individual communicating with the FDA should have experience and a successful track record interacting with regulatory authorities, preferably having brought products to the market. If you have not already done so, CPRIT recommends consulting the FDA Guidance for conducting formal meetings between the FDA and sponsors or applicants of PDUFA Products (available here: https://www.fda.gov/media/109951/download).
b. The timing of development meetings with regulatory authorities.
c. The possibility of a Priority Review by the FDA.
d. Whether to pursue an accelerated approval pathway.

   NOTE: The company should make this decision at the pre-IND stage since it severely truncates the timeline for all activities and will impact the time required for CMC development.

e. Whether the applicant is planning to apply for "Breakthrough Therapy Designation" and/or "Regenerative Medicine Advanced Therapy Designation" in the first trial assessing clinical efficacy. This decision impacts the data generated to pursue these potential paths.
f. Whether the applicant is pursuing "Orphan Drug Designation" if the intended marketed patient population (as defined by the TPP) has a prevalence of less than 200,000 patients

in the US, less than 50,000 patients in Japan, or a prevalence of not more than 5 in 10,000 in the EU.

NOTE: Combination US/EU applications may be prepared and submitted simultaneously to FDA and EMA.

g. Whether the applicant has prepared a Pediatric Development Plan.

NOTE: The company should consider this prior to conducting the end of phase 2 (EOP2) meeting with FDA. The company must submit the initial Pediatric Study Plan to FDA within 60 calendar days of completing the EOP2 meeting, or the EOP1 meeting if the product is developed using the Accelerated Approval Pathway.

8.8.10. Regulatory Correspondence Documentation (no page limit)

Applicants must upload as a standalone document copies of any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (eg, FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application. This is a continuing obligation that extends over the course of the review process. If the applicant receives meeting minutes after submitting the application but before CPRIT has made a final decision on the application, the applicant should contact the CPRIT Helpdesk (see section 10.1) for assistance on filing the additional information.

8.9. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies must raise substantial funds from other sources to fully fund development. Investors seek financial returns on their investment. An applicant should convince CPRIT that this project has investment return potential based on its risk profile sufficient to raise external capital.

CPRIT review typically focuses on size of market opportunity, development path, and key risk issues. The reviewers will evaluate company applicants based not only on the status of the components of the business plan but also on whether the company acknowledges current weaknesses and gaps and outlines a plan to address them.

The business plan consists of the business rationale overview and summaries of the following key development issues listed below. The business plan section may request some of the information that the applicant has included in the IPDP. To the extent possible, avoid duplication, redundancy, or references to the IPDP in favor of summarizing the information in the business plan.

8.9.1. Business Rationale (maximum 2 pages)

Provide the business rationale for investing in this project. Successful applicants will provide a thoughtful, careful, and succinct business justification explaining why this program is an appropriate investment of CPRIT and private funds.

8.9.2. Product and Market (maximum 1 page)

While the applicant will also provide information on the product and potential market when creating the IPDP required pursuant to section 8.8, including an overview of the product and method of delivery, describing the unmet medical need, and explaining the potential market in this section provide context for rest of the business plan.

a. Explain the unmet medical need with particular focus on patient populations contemplated for initial target indication(s): incidence/prevalence, life expectancy/survival, morbidity, annual mortality figures. Assuming the successful achievement of development objectives, describe how the intended product significantly addresses an unmet medical need in the treatment (including supportive care) and prognosis or prevention of cancer.
b. Describe the initial target market and how the product fits within the SOC, ie, primary therapy, second-line therapy, adjunctive to current therapies. Patient populations should be broadly comparable to those included in the pivotal trials. Define patient population sizes by market segments.

8.9.3. Competition and Value Proposition (maximum 1 page)

Provide an overview of the competitive environment (current and anticipated) and how the envisioned product will compete in the marketplace. Detail how the clinical utility (efficacy, safety, cost, etc) of this therapy compares with current SOC and forecast for potential future therapies. A clear delineation of competitive advantages, including supporting summary data, is

important.

8.9.4. Clinical and Regulatory Plans (maximum 1 page)

Provide an overview of the regulatory strategy, including preclinical and clinical activities and the regulatory pathway for major markets.

a. Include summary descriptions of regulatory communications (including all interactions to date with the FDA) and a description of how the company incorporated feedback from regulatory authorities.
b. If the application includes clinical research, present a plan to achieve realistic accrual rates of patients that meet the inclusion/exclusion criteria within the proposed timeline.

8.9.5. Pricing and Reimbursement (maximum 1 page)

Provide an overview of the projected 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.

8.9.6. Commercial Strategy (maximum 1 page)

Provide an overview of the company's financial projections and how the company plans to generate a return on this investment.

a. Describe how the company plans to bring the product to market. Information on targeted physicians, sales channels, etc, is helpful.
b. Alternatively, if the company's plan includes acquisition by a larger pharmaceutical company, provide an overview of similar transactions.

8.9.7. Risk Analysis (maximum 1 page)

Describe the specific risks inherent to the product plan and how the company plans to mitigate those risks. Key risk issues typically include efficacy versus competitors, toxicity, clinical trial implementation and conduct, FDA approval, dosage and delivery, CMC/synthesis, changing competitive environment, etc.

8.9.8. Funding to Date (This section may exceed 1 page, if necessary)

Provide an overview of the funding received by the company, including a list of funding sources

and a comprehensive capitalization table that comprises all parties with investments, stock, or rights in the company. CPRIT provides a template for a capitalization table in the application materials that the applicant **must** use when completing the application. The applicant must list identities of all parties and may exceed the 1-page limit if necessary to fully capture all funding sources. It is not appropriate to list any funding source as anonymous.

8.9.9. Company Financial Overview (maximum 1 page)

Please describe the company's financial condition including cash on hand, runway, burn rate, expenses, debt, working capital and any other metric that would provide insight into the company's finances.

8.9.10. Intellectual Property (IP)/Freedom to Operate (maximum 1 page)

a. List patents/patent applications together with jurisdictions, ownership/licensing aspects, status, and filing and expiration dates.
b. Indicate by patent/patent application the nature of key claims, viz, COM, methods, uses, formulation based, and what specifically would such claims prevent a competitor from doing. In this respect, include a discussion of the ease of workaround by a potential competitor.
c. For future/anticipated patent filings, indicate whether such filings will be continuation in part as opposed to divisional or novel/standalone patents.
d. Discuss potential for exclusivity as well as the potential contribution of trade secrets to protection from competition.
e. Describe freedom to operate, licensing status/plans.

8.9.11. Management Team and Key Personnel (maximum 1 page)

The applicant's management team should be composed of individuals who have the appropriate level of experience in developing and commercializing products. The team should include appropriate disciplinary experts in product engineering, clinical development, nonclinical development, product design, manufacturing, regulatory strategy, commercialization, and fundraising. An experienced program manager who has coordinated product development activities to product approval is desired. Team members, either consultants or company

employees, must have sufficient time to devote to development activities allocated in the application.

For each member of the senior management and scientific team, provide a paragraph summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Also indicate the percentage of the person's time devoted to the project. The time indicated by the company is an obligatory commitment, regardless of whether 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.

Provide the same information for other key personnel 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.) NOTE: While the applicant should identify all participants who meet these criteria as "key personnel," CPRIT expects that the applicant will keep to a minimum the number individuals designated as key personnel.

8.10. Biographical Sketches of Key Scientific Personnel (maximum 8 pages)

Provide a biographical sketch for up to 4 key scientific personnel describing their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. CPRIT provides an optional "Product Development Research Programs: Biographical Sketch" template for the applicant's use. The NIH biographical sketch format is also appropriate.

8.11. Commitment to Texas (maximum 1 page)

Describe the company's commitment to locating in Texas and maintaining its business presence in the state. Please identify the criteria specified in section 4.1 "Award Recipients Must Be Texas-Based, For-Profit Companies" that the company will fulfill if it receives a CPRIT award.

If the applicant is not currently Texas based, provide a timetable with key dates indicating the applicant's plan and commitment to relocate the company to Texas. In addition, describe which personnel and management will be headquartered in Texas.

8.12. Budget

This is a 3-year funding program, with an opportunity to extend the duration of contract to fully expend awarded funds. All requested funds must be well justified; CPRIT will award financial support based upon the breadth and nature of the project proposed, the transparency of the budget, and the extent to which the company will spend funds in Texas. The total budget included in the full application must not vary significantly from the anticipated budget request included in the applicant's preliminary application. For purposes of this section, "vary significantly" means that the total budget in the full application must not exceed the anticipated budget request in the preliminary application by more than 5%.

The budget must align with the proposed G&Os. CPRIT will disburse funds in tranches tied to the company's achievement of the contractual G&Os.

When preparing the requested budget, applicants should consider the following:

a. Identify the specific equipment that the company proposes to purchase with grant funds. Items that the company includes in the "equipment" budget line should have a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit.
b. Texas Health & Safety Code Section 102.203(d) law limits the amount of grant funds that companies may spend on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). CPRIT's Administrative Rules provide guidance regarding indirect cost recovery.
c. The total amount of CPRIT funds allowed for an individual's FY25 annual salary is $225,000. An individual may request salary proportional to the percent effort up to a maximum of $225,000. Companies may pay salary amounts exceeding this limit from matching funds. The salary amount does not include fringe benefits. Additionally, CPRIT permits annual salary adjustments of up to a 3% increase for Years 2 and 3, up to the cap of $225,000. CPRIT may revise the FY25 salary cap and future salary caps at its discretion.

The Budget section is composed of 4 subtabs:

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 the company requests funding for a role that the company has not yet filled at the time of submission, the applicant should note "new hire" as name.

b. **Detailed Budget for Year 1:** 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. This section should include only the amount requested from CPRIT. DO NOT include the amount of the matching funds or the budget for the entire proposed period of performance.

c. **Budget for Entire Proposed Period of Performance:** Provide the amount requested from CPRIT for direct costs for all subsequent years. CARS will automatically populate the amounts for *Budget Year 1* based on the information provided in the previous subtabs. This section should include only the amount requested from CPRIT. DO NOT include the amount of the matching funds.

d. **Budget Justification:** The budget should align with the proposed G&Os. 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. For projects that involve CROs or other third parties providing clinical trial services, include quotations/estimates from the CRO/other third parties. If travel costs will include out-of-state or international travel, make that clear here. This section should include CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds.

9. AWARD CONTRACTS

9.1. Overview

Texas law requires that CPRIT award grant funds via a contract between the company and CPRIT. Contract negotiation commences after the CPRIT Oversight Committee votes to approve an application for a grant award. Texas law specifies several contract terms that CPRIT must include in the executed agreement, including terms relating to revenue sharing and IP rights, matching funds, and required reporting for fiscal, progress, and compliance.

CPRIT recommends that applicants review CPRIT's Administrative Rules and its related Policies & Procedures Guide (available at www.cprit.texas.gov) for information describing

contractual requirements, fiscal and program progress reporting, and limitations on the use of CPRIT grant funds. This RFA highlights information regarding revenue sharing and matching funds below.

9.2. Revenue-Sharing Terms

The contract will include a revenue-sharing agreement. CPRIT publishes its standard revenue-sharing terms on its website at https://cprit.texas.gov/our-programs/product-development-research. CPRIT will include these standard revenue-sharing terms in the award contract unless parties negotiate different revenue-sharing terms that are in the interest of the state and the company.

9.3. Matching Funds

CPRIT requires a company receiving a CPRIT Product Development Research Award to pay a portion of the overall project expenses using money under the company's control. The company's expenditure of these "matching funds" must take place at the same time the company is drawing down CPRIT funds; there is no credit toward the CPRIT matching funds requirement for in-kind expenses or expenditures made prior to the CPRIT award. The company may fulfill its matching funds commitment on a year-by-year basis.

The company demonstrates that it has available matching funds at the time CPRIT disburses funds pursuant to an executed award contract, not when the company submits the CPRIT application.

CPRIT sets the amount of matching funds the company must contribute toward the project based on the total amount of CPRIT funds committed to the company:

- For companies receiving $20 million or less from CPRIT (inclusive of previous CPRIT awards), the company must dedicate to the project at least $1 of funds under the company's control for every $2 of CPRIT grant award funds.
- A company approved for 1 or more CPRIT product development grants that together total a commitment of more than $20 million must increase their matching fund obligation to at least $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 CPRIT's matching funds policy, the company must dedicate at least $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 1 or more CPRIT product development grants that together total a commitment of more than $30 million must contribute at least $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.

10. CONTACT INFORMATION

10.1. Helpdesk

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration and online submission of applications. Helpdesk staff cannot 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. For "Frequently Asked Technical Questions," please go here.

Hours of operation:	Monday through Friday, 8:00 AM to 6:00 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

10.2. Programmatic Questions

The CPRIT Product Development Program Manager will answer questions regarding CPRIT's Product Development Program awards and review process, including questions regarding the scientific, product development, and business aspects of applications. For "Frequently Asked Programmatic Questions," please go here.

Tel:	512-305-7676
Email:	proddev@cprit.texas.gov
Website:	www.cprit.texas.gov

11. APPENDIX – REVIEWER EVALUATION GUIDELINES

11.1. Primary Review Criteria (Scored)

11.1.1. Unmet Medical Need

a. Assuming successful accomplishment of development objectives, as reflected in the TPP, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
b. 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?

11.1.2. Target Validation

a. If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
b. Has engagement of the target with the agent been demonstrated by biochemical assay?
c. What is the potency of the agent?
d. Are there validated downstream PD markers of target modulation?
e. 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?
f. Is the target uniquely or substantially overexpressed by tumor versus normal cells?
g. Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
h. Has the company's demonstration of target validation been externally/independently confirmed?
i. 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?

11.1.3. Preclinical Characterization: Pharmacodynamic (PD) Proof of Concept

a. Considering in vivo preclinical PD 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 SOC for refractory versus drug-naïve tumors? At the time of treatment initiation, were tumors established and measurable, or was treatment initiated shortly after tumor inoculation?

b. 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?
c. Have results of preclinical efficacy studies carried out by the company been externally/independently confirmed?
d. Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
e. How strongly does the preclinical PD profile support the clinical efficacy expectations reflected in the TPP?

11.1.4. Preclinical Characterization: Safety

a. How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
b. Has the agent undergone CEREP-type screening for interactions with targets with known safety liabilities, eg, CYP 450, hERG?
c. Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
d. Can exposures associated with substantial antitumor efficacy/PD effects be achieved safely and in vivo?
e. Do preclinical PK studies indicate potential for clinical safety issues, eg, accumulation, variability, lack of dose proportionality?
f. Have PK/PD issues been investigated with alternate dosing schedules in order to optimize the therapeutic index of the agent?
g. Are there any issues with the distribution or metabolism of the agent?
h. 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?

11.1.5. Pharmaceutical Properties/Chemistry and Pharmacy

a. 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?
b. 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?
c. Are there any issues with the stability of the drug substance or the drug product?
d. Is there scope for further lead optimization through structure-activity studies?
e. 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?
f. Have analytical methods been adequately developed?
g. Has the (lead) protein been adequately characterized biochemically, immunogenetically, and biophysically? Has absence of aggregate formation been demonstrated in stability studies?

11.1.6. Development Plan/Regulatory Aspects

a. Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
b. Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions (US/EU)? Do development proposals reflect specific regulatory authority input; eg, from pre-IND interactions? Alternatively, has regulatory authority interaction been insufficient so far?
c. In the case of clinical studies, are patient populations adequately described and consistent with those representing the initial target indication(s)?
d. Are efficacy end points appropriate for study designs? Is the sample size statistically adequately justified in terms of the target effect size?
e. In the case of potentially pivotal clinical trials, moreover, are the proposed primary efficacy end points and target effect sizes consistent with regulatory precedence?

f. Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
g. 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?
h. 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?
i. Are development milestones clear and adequately described? Is the overall project timeline realistic?

11.1.7. Competitive Analysis

a. 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?
b. 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?

11.1.8. Intellectual Property (IP)/Freedom to Operate

a. Have IP and freedom-to-operate aspects been addressed in the application?
b. Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
c. Are there opportunities for meaningful patent life extension?
d. Has the applicant secured appropriate licenses conferring freedom to operate?

11.1.9. Chemistry, Manufacturing, and Controls (CMC)

a. How advanced is CMC and manufacturing development?
b. Are there any sourcing issues?
c. Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?

d. Are there significant technical difficulties within CMC/manufacturing scaleup still to be addressed?

11.1.10. Business/Commercial Aspects

a. 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?
b. 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?
c. 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?
d. 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?

11.1.11. Management Team

a. Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
b. 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?
c. Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

11.2. Secondary Review Criteria (Unscored) Budget and Duration of Support

a. Are the budget and duration of support appropriate for the program of studies described in the application?
b. Is there sufficient clarity in the budget proposal as to how funds will be expended?

c. Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
d. 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?

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6)
Observation Report

Report No.	2024-06-10 PDPRE - 25-1.6
Program Name:	Product Development Research
Panel Name:	FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6)
Panel Date:	June 10, 2024
Report Date:	June 13, 2024

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 FY25-1.6 PDR Prelim App Review Meeting (PDPRE - 25-1.6) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on June 10, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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: Four (4)
- 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.

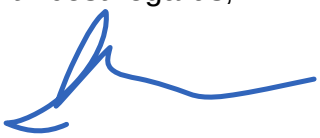
CONCLUSION

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.

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, CRMA, 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)
FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.1
Program Name:	Product Development Research
Panel Name:	FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.1 PDR Prelim App Review Meeting (PDPRE-25-1.1) meeting. The meeting was chaired by Kristine Swiderek and conducted via videoconference on June 12, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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 was one (1) Conflict 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, CRMA, 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)
FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.3
Program Name:	Product Development Research
Panel Name:	FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.3 PDR Prelim App Review Meeting (PDPRE-25-1.3) meeting. The meeting was chaired by Renzo Canetta and conducted via videoconference on June 12, 2024.

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
- Panelists: One (1) discussion lead and three (3) expert 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 was one (1) 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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5)
Observation Report

Report No.	2024-06-12 PDPRE-25-1.5
Program Name:	Product Development Research
Panel Name:	FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5)
Panel Date:	June 12, 2024
Report Date:	June 18, 2024

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 FY25-1.5 PDR Prelim App Review Meeting (PDPRE-25-1.5) meeting. The meeting was chaired by Roy Cosan and conducted via videoconference on June 12, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) application were discussed and seven (7) applications were not discussed
- Panelists: One (1) discussion lead, and three (3) expert 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 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, CRMA, 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)
FYFY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2)
Observation Report

Report No.	2024-06-13 PDPRE-25-1.2
Program Name:	Product Development Research
Panel Name:	FY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2)
Panel Date:	June 13, 2024
Report Date:	June 18, 2024

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 FY25-1.2 PDR Prelim App Review Meeting (PDPRE-25-1.2) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on June 13, 2024.

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) application were discussed and six (6) applications were not discussed
- Panelists: One (1) discussion lead and three (3) expert 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 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, CRMA, 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)
FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8)
Observation Report

Report No.	2024-06-14 PDPRE-25-1.8
Program Name:	Product Development Research
Panel Name:	FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8)
Panel Date:	June 14, 2024
Report Date:	June 18, 2024

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 FY25-1.8 PDR Prelim App Review Meeting (PDPRE-25-1.8) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on June 14, 2024.

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: Three (3) application were discussed and eight (8) applications were not discussed
- Panelists: One (1) discussion lead and three (3) expert 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 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.

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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9)
Observation Report

Report No.	2024-06-18 PDPRE-25-1.9
Program Name:	Product Development Research
Panel Name:	FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9)
Panel Date:	June 18, 2024
Report Date:	June 21, 2024

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 FY25-1.9 PDR Prelim App Review Meeting (PDPRE-25-1.9) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on June 18, 2024.

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: Eleven (11) applications were discussed
- Panelists: One (1) discussion lead, and three (3) expert 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 was one (1) Conflict 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, CRMA, 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)
FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7)
Observation Report

Report No.	2024-06-20 PDPRE-25-1.7
Program Name:	Product Development Research
Panel Name:	FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7)
Panel Date:	June 20, 2024
Report Date:	June 21, 2024

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 FY25-1.7 PDR Prelim App Review Meeting (PDPRE-25-1.7) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on June 20, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed and eight (8) applications were not discussed
- Panelists: One (1) discussion lead, and four (4) expert 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: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict 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, CRMA, 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)
25.1 Product Development Panel-1 (25.1 _PDP-1)
Observation Report

Report No.	2024-09-06 25.1_PDP-1
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-1 (25.1 _PDP-1)
Panel Date:	September 6, 2024
Report Date:	September 9, 2024

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 25.1 Product Development Panel-1 (25.1_PDP-1) meeting. The meeting was chaired by Tian Yu and conducted via videoconference on September 6, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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, CRMA, 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)
25.1 Product Development Panel-2 (25.1_PDP-2)
Observation Report

Report No.	2024-09-09 25.1_PDP-2
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-2 (25.1 _PDP-2)
Panel Date:	September 9, 2024
Report Date:	September 10, 2024

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 25.1 Product Development Panel-2 (25.1_PDP-2) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on September 9, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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: Three (3)
- 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, CRMA, 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)
25.1 Product Development Panel-3 (25.1 _PDP-3)
Observation Report

Report No.	2024-09-09 25.1_PDP-3
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-3 (25.1 _PDP-3)
Panel Date:	September 9, 2024
Report Date:	September 10, 2024

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 25.1 Product Development Panel-3 (25.1_PDP-3) meeting. The meeting was chaired by Renzo Canetta and conducted via videoconference on September 9, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Product Development Panel-4 (25.1_PDP-4)
Observation Report

Report No.	2024-09-10 25.1_PDP-4
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-4 (25.1 _PDP-4)
Panel Date:	September 10, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-4 (25.1_PDP-4) meeting. The meeting was chaired by Roy Cosan and conducted via videoconference on September 10, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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 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, CRMA, 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)
25.1 Product Development Panel-5 (25.1_PDP-5)
Observation Report

Report No.	2024-09-11 25.1_PDP-5
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-5 (25.1 _PDP-5)
Panel Date:	September 11, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-5 (25.1_PDP-5) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on September 11, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) 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: Two (2)
- 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, CRMA, 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)
25.1 Product Development Panel-6 (25.1_PDP-6)
Observation Report

Report No.	2024-09-12 25.1_PDP-6
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-6 (25.1 _PDP-6)
Panel Date:	September 12, 2024
Report Date:	September 16, 2024

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 25.1 Product Development Panel-6 (25.1_PDP-6) meeting. The meeting was chaired by David Russler-Germain and conducted via videoconference on September 12, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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, CRMA, 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)
25.1 Product Development Panel-7 (25.1 _PDP-7)
Observation Report

Report No.	2024-09-13 25.1_PDP-7
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-7 (25.1 _PDP-7)
Panel Date:	September 13, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-7 (25.1_PDP-7) meeting. The meeting was chaired by Ginette Serrero and conducted via videoconference on September 13, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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, CRMA, 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)
25.1 Product Development Panel-8 (25.1 _PDP-8)
Observation Report

Report No.	2024-09-13 25.1_PDP-8
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-8 (25.1 _PDP-8)
Panel Date:	September 13, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-8 (25.1_PDP-8) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on September 13, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 was 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, CRMA, 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)
25.1 Product Development Panel-9 (25.1 PDP-9)
Observation Report

Report No.	2024-09-16 25.1_PDP-9
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-9 (25.1 _PDP-9)
Panel Date:	September 16, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-9 (25.1_PDP-9) meeting. The meeting was chaired by Jill Kolesar and conducted via videoconference on September 16, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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 was 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, CRMA, 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)
25.1 Product Development Panel-10 (25.1_PDP-10)
Observation Report

Report No.	2024-09-16 25.1_PDP-10
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-10 (25.1 _PDP-10)
Panel Date:	September 16, 2024
Report Date:	September 18, 2024

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 25.1 Product Development Panel-10 (25.1_PDP-10) meeting. The meeting was chaired by Jun Deng and conducted via videoconference on September 16, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-11 (25.1_PDP-11)
Observation Report

Report No.	2024-09-17 25.1_PDP-11
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-11 (25.1 _PDP-11)
Panel Date:	September 17, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-11 (25.1_PDP-11) meeting. The meeting was chaired by Steven Weinstein and conducted via videoconference on September 17, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-12 (25.1_PDP-12)
Observation Report

Report No.	2024-09-17 25.1_PDP-12
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-12 (25.1 _PDP-12)
Panel Date:	September 17, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-12 (25.1_PDP-12) meeting. The meeting was chaired by Christopher Carpenter and conducted via videoconference on September 17, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-13 (25.1_PDP-13)
Observation Report

Report No.	2024-09-18 25.1_PDP-13
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-13 (25.1 _PDP-13)
Panel Date:	September 18, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-13 (25.1_PDP-13) meeting. The meeting was chaired by William Gmeiner and conducted via videoconference on September 18, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-14 (25.1_PDP-14)
Observation Report

Report No.	2024-09-19 25.1_PDP-14
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-14 (25.1 _PDP-14)
Panel Date:	September 19, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-14 (25.1_PDP-14) meeting. The meeting was chaired by Arnab Ghosh and conducted via videoconference on September 19, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-15 (25.1_PDP-15)
Observation Report

Report No.	2024-09-19 25.1_PDP-15
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-15 (25.1 _PDP-15)
Panel Date:	September 19, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-15 (25.1_PDP-15) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on September 19, 2024.

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) application was discussed
- Panelists: One (1) panel chair, six (6) expert reviewers, and one (1) advocate reviewer
- 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 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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-16 (25.1_PDP-16)
Observation Report

Report No.	2024-09-20 25.1_PDP-16
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-16 (25.1 _PDP-16)
Panel Date:	September 20, 2024
Report Date:	September 20, 2024

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 25.1 Product Development Panel-16 (25.1_PDP-16) meeting. The meeting was chaired by Matthew Spear and conducted via videoconference on September 20, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-17 (25.1_PDP-17)
Observation Report

Report No.	2024-09-23 25.1_PDP-17
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-17 (25.1 _PDP-17)
Panel Date:	September 23, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-17 (25.1_PDP-17) meeting. The meeting was chaired by Alan West and conducted via videoconference on September 23, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-18 (25.1_PDP-18)
Observation Report

Report No.	2024-09-24 25.1_PDP-18
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-18 (25.1 _PDP-18)
Panel Date:	September 24, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-18 (25.1_PDP-18) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on September 24, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-19 (25.1_PDP-19)
Observation Report

Report No.	2024-09-25 25.1_PDP-19
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-19 (25.1 _PDP-19)
Panel Date:	September 25, 2024
Report Date:	September 26, 2024

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 25.1 Product Development Panel-19 (25.1_PDP-19) meeting. The meeting was chaired by Kristine Swiderek and conducted via videoconference on September 25, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-20 (25.1_PDP-20)
Observation Report

Report No.	2024-09-26 25.1_PDP-20
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-20 (25.1 _PDP-20)
Panel Date:	September 26, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel-20 (25.1_PDP-20) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on September 26, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: One (1)
- 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, CRMA, 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)
25.1 Product Development Panel - 21 (25.1_PDP - 21)
Observation Report

Report No.	2024-09-26 25.1_PDP - 21
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 21 (25.1 _PDP - 21)
Panel Date:	September 26, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel - 21 (25.1_PDP - 21) meeting. The meeting was chaired by Karen Stein and conducted via videoconference on September 26, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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.

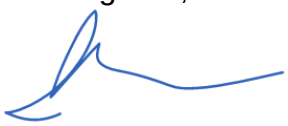
CONCLUSION

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, CRMA, 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)
25.1 Product Development Panel - 22 (25.1_PDP - 22)
Observation Report

Report No.	2024-09-27 25.1_PDP - 22
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 22 (25.1 _PDP - 22)
Panel Date:	September 27, 2024
Report Date:	October 1, 2024

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 25.1 Product Development Panel - 22 (25.1_PDP - 22) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on September 27, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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 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, CRMA, 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)
25.1 Product Development Panel-7 DD (25.1 PDP-7 DD)
Observation Report

Report No.	2024-10-14 25.1_PDP-7 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-7 DD (25.1 _PDP-7 DD)
Panel Date:	October 14, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-7 DD (25.1_PDP-7 DD) meeting. The meeting was chaired by Ginette Serrero and conducted via videoconference on October 14, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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, CRMA, 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)
25.1 Product Development Panel-9 DD (25.1 PDP-9 DD)
Observation Report

Report No.	2024-10-14 25.1_PDP-9 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-9 DD (25.1 _PDP-9 DD)
Panel Date:	October 14, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-9 DD (25.1_PDP-9 DD) meeting. The meeting was chaired by Jill Kolesar and conducted via videoconference on October 14, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-5 DD (25.1 PDP-5 DD)
Observation Report

Report No.	2024-10-15 25.1_PDP-5 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-5 DD (25.1 _PDP-5 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-5 DD (25.1_PDP-5 DD) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) and one (1) who remained in the Waiting Room

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.

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With best regards,

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

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT) 25.1 Product Development Panel-6 DD (25.1 PDP-6 DD) Observation Report

Report No.	2024-10-15 25.1_PDP-6 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-6 DD (25.1 _PDP-6 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-6 DD (25.1_PDP-6 DD) meeting. The meeting was chaired by David Russler-Germain and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, and five (5) expert 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Product Development Panel-8 DD (25.1 PDP-8 DD)
Observation Report

Report No.	2024-10-15 25.1_PDP-8 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-8 DD (25.1 _PDP-8 DD)
Panel Date:	October 15, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-8 DD (25.1_PDP-8 DD) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on October 15, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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, CRMA, 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)
25.1 Product Development Panel-12 DD (25.1 PDP-12 DD)
Observation Report

Report No.	2024-10-16 25.1_PDP-12 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-12 DD (25.1 _PDP-12 DD)
Panel Date:	October 16, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-12 DD (25.1_PDP-12 DD) meeting. The meeting was chaired by Christopher Carpenter and conducted via videoconference on October 16, 2024.

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
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Two (2) who remained in the Waiting Room

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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Panel-2 DD (25.1 _PDP-2 DD)
Observation Report

Report No.	2024-10-17 25.1_PDP-2 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel-2 DD (25.1 _PDP-2 DD)
Panel Date:	October 17, 2024
Report Date:	October 17, 2024

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 25.1 Product Development Panel-2 DD (25.1_PDP-2 DD) meeting. The meeting was chaired by Collin Turnbull and conducted via videoconference on October 17, 2024.

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
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: One (1)

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, CRMA, 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)
25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD)
Observation Report

Report No.	2024-10-18 25.1_PDP-20 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD)
Panel Date:	October 18, 2024
Report Date:	October 22, 2024

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 25.1 Product Development Panel - 20 DD (25.1 PDP-20 DD) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on October 18, 2024.

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) application was discussed
- Panelists: One (1) panel chair, four (4) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- McDermott, Will & Emery Consultants staff: Zero (0)

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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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) 25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD)Observation Report

Report No.	2024-10-21 2.51_PDP-22 DD
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD)
Panel Date:	October 21, 2024
Report Date:	October 23, 2024

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 25.1 Product Development Panel - 22 DD (25.1 PDP-22 DD) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on October 21, 2024.

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) application was discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and one (1) advocate reviewer
- 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
- Boyds Consultants staff: One (1) who remained in the Waiting Room
- Norton Rose Fulbright Law Firm Consultants staff: Three (3) who remained in the Waiting Room

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.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CRMA, 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)
25.1 Product Development Review Council Meeting (25.1 PDRC)
Observation Report

Report No.	2024-10-28 25.1 PDRC
Program Name:	Product Development Research
Panel Name:	25.1 Product Development Review Council Meeting (25.1 PDRC)
Panel Date:	October 28, 2024
Report Date:	October 30, 2024

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 25.1 Product Development Review Council Meeting (25.1 PDRC) . The meeting was chaired by Jack Geltosky and conducted via videoconference on October 28, 2024.

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: Nine (9) applications were discussed
- Panelists: One (1) panel chair, one (1) panel vice chair, and eight (8) product development review council memebers
- 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 (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.

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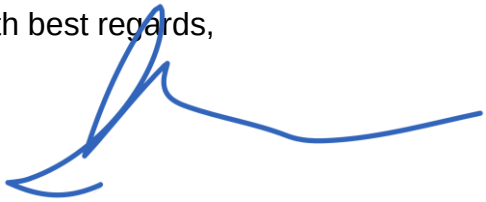
With best regards,



Mara Ash, CIA, CGAP, CGFM, CRMA, 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 25.1
Awards Announced at the November 20, 2024, Oversight Committee Meeting

The following table 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 25.1 include those received in response to the following Requests for Applications: *SEED Awards for Product Development Research; Texas Diagnostic and Devices Company Awards; Texas Therapeutics Company Awards;* and *Texas New Technology Company 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:			
DP250159	Thapar, Neil C	Barricade Therapeutics, Corp	Rosenfeld, Craig
Applications not considered by the PIC or Oversight Committee:			
DP250115 (preliminary)	Whitney, Duncan	Gregor Diagnostics	Yu, Tian
DP250071 (preliminary)	Li, Yong	SOTLA THERAPEUTICS LLC	Anderson, Karen
DP250075 (preliminary)	Allinson, Bryan	Vanquish Bio	Geltosky, Jack
DP250005 (preliminary)	Carter, Kenneth	Black Canyon Bio, Inc.	Akhavan, David

T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	T.A.C. § 702.19 WAIVER APPROVAL FOR DR. KEN SMITH
DATE:	OCTOBER 29, 2024

Summary

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I have granted Chief Product Development Officer Dr. Ken Smith a waiver from the general prohibition against communicating with a grant applicant while CPRIT is accepting and reviewing applications. The waiver applies to communication with the nine companies that the Product Development Review Council (PDRC) has recommended for grant awards in review cycle 25.1. Approving the waiver promotes CPRIT's objectives and does not give one or more applicants an unfair advantage. No Oversight Committee action related to this waiver is necessary.

Discussion

The Chief Product Development Officer is a statutorily mandated member of the Program Integration Committee (PIC). Texas Administrative Code § 702.19 prohibits substantive communication between the grant applicant and a member of the peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The communication restriction is one way that we prevent even the appearance of unequal treatment in the grant review process. However, the rule provides a process for the CEO to waive the communication restriction in specific circumstances if doing so is in the interest of CPRIT's process and does not give any applicant an unfair advantage.

Approving this waiver allows Dr. Smith to negotiate reductions in proposed budgets with each company prior to Oversight Committee approval. Granting the waiver will not favor any applicant or provide an unfair advantage.

The Oversight Committee does not need to take any action regarding this waiver. Dr. Smith's waiver will be part of the grant record for the FY 2025 product development awards.

High Level Summary of Due Diligence

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Telos Biotechnology for $2,778,945.

No Contingencies

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.

Telos Biotechnology aims to improve CAR T-cell therapy outcomes with TELOVANCE, a telomerase-based treatment that extends telomeres during CAR T-cell manufacturing to delay cell senescence and enhance efficacy. As telomere shortening limits CAR T-cell longevity, TELOVANCE addresses this challenge by selectively extending telomeres in CAR T-cells, improving their therapeutic potential without risk of immortalization.

TELOVANCE's transient telomere extension increases cell survival and cytotoxicity, tackling a key limitation in CAR T-cell therapies, where only 50% of patients achieve long-term remission. This innovation, validated in both in-vitro and in-vivo studies, is positioned to transform CAR T-cell therapy by boosting the performance and durability of the manufactured cells.

The project will transition TELOVANCE production to GMP standards and conduct in-vivo studies for expanded safety testing. Additional studies will explore TELOVANCE's potential in other cell types, expanding its applications beyond hematologic cancers.

CPRIT support will allow Telos to advance TELOVANCE toward commercial readiness and enhance Texas's biotech ecosystem. By establishing a manufacturing presence in Texas, Telos can drive cell therapy innovations and create economic impact through high-value therapeutic developments.

Select Reviewer Comments

"The lack of significant long-term responses in many CAR-T treated patients is a genuine unmet medical need, and Telos is positioned to potentially improve and increase those long-term responses."

"Telovance-treated CAR T-cells showed an increase in persistence six months after injection into mice during pilot safety studies. This is a critically important and clinically relevant result."

"The application proposes the development of an innovative technology that could potentially impact the treatment of cancer and benefit cancer patients greatly. The applicants explain the unique role of Telovance in that it improves the efficacy and durability of cell and gene therapies."

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Ypsilon Therapeutics for $2,727,500.

No Contingencies

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.

Ypsilon Therapeutics is advancing TCR mimic (TCRm) x CD3 antibodies targeting the CT83 peptide, selectively expressed in various solid tumors, to overcome limitations in immune checkpoint inhibitor efficacy. This novel immunotherapy directs T cells to specifically target CT83-expressing tumor cells, enhancing safety and precision.

Leveraging Alloy Therapeutics' TCR discovery platform, Ypsilon has developed TCRm antibodies with high affinity for CT83, engineering them into bispecific CD3 T cell engagers. This approach selectively targets malignant tissues, addressing the unmet need in solid tumor treatment.

This project will develop and validate the TCRm CD3 engagers through bispecific engineering and in-vivo studies in xenograft models, with CPRIT support accelerating preclinical milestones. The project will also facilitate Ypsilon's move to Houston, where they plan to collaborate with MDACC.

CPRIT funding will enable Ypsilon to advance this promising treatment, positioning Texas as a leader in solid tumor immunotherapy and providing new options for patients resistant to existing therapies.

Select Reviewer Comments

"Despite advancements in anti-cancer therapies... the prognosis for patients with solid tumors... continues to be poor. Addressing this need is indeed urgently needed."

"If successful, Ypsilon's bispecific TCRm T cell engager may have a meaningful impact in addressing unmet need. The technologies that result in the first drug could be leveraged to make other engagers that address other HLA and other antigens."

"This proposal, if successful, will result in an innovative product that addresses unmet needs in multiple solid cancers. The upside is significant, and the team is as well-suited to successful execution as any small group could be."

SEED

The PDRC recommends that the PIC and Oversight Committee approve a Texas Seed Company Award for Product Development Research:

Erisyon, Inc. for $2,157,172.50

No Contingencies

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.

Erisyon is developing a fluorosequencing-based assay to predict immune checkpoint inhibitor (ICI) resistance in non-small cell lung cancer (NSCLC) patients. By measuring the PSME4 to PSMB10 ratio in immunoproteasomes, this biomarker can identify treatment-resistant tumors, guiding effective therapy selection.

This innovative assay provides absolute molecular quantitation and high sensitivity, enabling accurate antigenicity assessments. With fluorosequencing's capability, Erisyon addresses limitations in current mass spectrometry and antibody assays, enhancing precision in predicting ICI outcomes.

The project will validate the assay's clinical utility through controlled and patient samples, with benchmarking against FDA-approved assays. CPRIT support will enable Erisyon's scale-up and regulatory compliance activities, advancing toward FDA approval.

CPRIT funding will help Erisyon establish a high-impact diagnostic tool in Texas, supporting oncologists with improved patient stratification tools and furthering Texas's contributions to precision cancer diagnostics.

Select Reviewer Comments

"The applicants target a significant challenge in oncology: the early identification of non-small cell lung cancer (NSCLC) patients likely to benefit from checkpoint inhibitor therapy. … a newly developed test, in combination with the success of immune checkpoint inhibitors (ICIs), could benefit a substantial number of cancer patients."

"If successful, the project could significantly expand the eligible patient population for ICI therapy and aid in the development of more effective ICI therapies by offering accurate insights into tumor antigenicity."

"By specifically targeting the PSME4/PSMB10 ratio within tumor cells, this product directly indicates the tumor's status and its potential receptivity to ICI therapy, potentially overcoming a significant barrier in the current approach to cancer treatment."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Marker Therapeutics for $9,513,569.

No Contingencies

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.

Marker Therapeutics is advancing MT-601, a T cell therapy for metastatic pancreatic cancer (mPC), leveraging six tumor-associated antigens (mTAA) highly expressed in pancreatic cancer to reduce tumor escape and off-target effects. MT-601 is designed for outpatient administration, enhancing accessibility while minimizing toxicity, and has shown promising efficacy in lymphoma, with early pancreatic cancer trials indicating robust safety and initial efficacy.

MT-601's unique targeting mechanism allows it to recognize and kill tumor cells through native T cell receptors, addressing a critical need for more effective mPC treatments. Only 52% of patients are eligible for standard mPC chemotherapy due to high toxicity, making MT-601's non-toxic approach particularly valuable. The therapy's design avoids genetic engineering, providing a novel, safer immunotherapy alternative.

Marker's Phase 1 trial will assess MT-601 with FOLFIRINOX in mPC patients across multiple sites, including MD Anderson Cancer Center (MDACC). A dose-escalation phase and dose expansion cohort will evaluate safety and efficacy, with results supporting applications for Regenerative Medicine Advanced Therapy (RMAT) designation and facilitating progression to larger trials.

With CPRIT funding, Marker Therapeutics can advance MT-601 through clinical trials while expanding partnerships with Texas-based entities, supporting Texas's healthcare landscape with cutting-edge mPC treatments. The funding will expedite MT-601's path to market, offering new hope for patients with limited therapeutic options.

Select Reviewer Comments

"Given the unmet medical need of pancreatic cancer, the intended product will significantly address the treatment of this cancer."

"The company has obtained FDA orphan drug designation for MT-601 in treating metastatic pancreatic cancer, and preliminary clinical data show promising safety and efficacy."

"MT-601's target patient population, current clinical stage of development, excellent safety profile, potential for increased efficacy, and lack of genetic engineering gives MT-601 a considerable edge in the market."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Metaclipse Therapeutics for $6,080,245.

No Contingencies

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.

Metaclipse's Membrex vaccine, a personalized autologous immunotherapy, seeks to improve immune responses in head and neck squamous cell carcinoma (HNSCC) by overcoming resistance to immune checkpoint inhibitors (ICIs). Using tumor membrane vesicles (TMVs) from patient tumor tissue, Membrex combines tumor-specific antigens with potent immunostimulatory molecules to induce a more robust T-cell response.

Preclinical studies in HNSCC models have demonstrated Membrex's efficacy, showing increased T-cell infiltration, tumor growth reduction, and metastasis prevention. By sensitizing tumors to anti-PD-1 therapy, Membrex could extend the benefits of ICIs to a broader range of HNSCC patients who currently lack durable responses.

The Phase 1a/b clinical trial will assess Membrex's safety and efficacy in combination with ICIs, conducted at MDACC and additional Texas-based sites. GMP manufacturing will be supported by Texas-based CDMO Fujifilm Diosynth, ensuring operational continuity in the state.

CPRIT funding will enable Metaclipse to advance Membrex in Texas, establishing a base in Houston to drive clinical and operational growth. This support will boost Texas's role in personalized immunotherapy, advancing treatment options for HNSCC patients while fostering economic development.

Select Reviewer Comments

"Membrex vaccine immunotherapy has the potential to significantly address an unmet medical need in the treatment of recurrent HNSCC."

"The successful completion of the goals and objectives of this project will allow go / no-go decisions to be made about further clinical and product development, with strong potential for new drug products that can address current unmet medical needs."

"Membrex is poised to exercise one of many business strategies upon obtaining convincing clinical data in their Phase 2 study."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Barricade Therapeutics, Corp. for $14,005,034.65.

No Contingencies

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.

Barricade Therapeutics is developing TASIN-15, a novel therapy targeting the APC mutation (APCmut) prevalent in colorectal cancer (CRC), which is linked to cancer progression. TASIN-15 selectively inhibits Emopamil binding protein (EBP) with minimal off-target effects, offering a new therapeutic approach for advanced CRC patients.

With an 11% survival rate for metastatic CRC (mCRC), TASIN-15 presents a potential breakthrough by improving efficacy where standard therapies fall short. Preclinical studies show TASIN-15's favorable bioavailability, tissue penetration, and safety, paving the way for Phase 1 trials to establish dosage and efficacy.

Barricade seeks CPRIT funding to complete Phase 1 trials in advanced APCmut CRC patients, establishing TASIN-15's potential as a single-agent and combination therapy. The funding will also support Phase 1b expansion to assess broader therapeutic applications.

With CPRIT support, Barricade will demonstrate Texas's capacity for innovative cancer therapy, positioning TASIN-15 as a leading CRC treatment and strengthening Texas's biotech landscape through advanced clinical development.

Select Reviewer Comments

"Advanced colorectal cancer has a very poor 5-year survival rate. There are few effective, targeted treatments for these patients… A novel, targeted oral treatment would be a welcomed treatment option."

"If TASIN-15 is proven to be safe and effective in CRC, this new therapy would be an important step forward in treating this cancer."

"This therapeutic approach could offer a significant contribution to the management of colorectal cancer."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Orphagen for $10,213,909.

No Contingencies

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.

Orphagen Pharmaceuticals is developing OR-449, a small molecule antagonist targeting steroidogenic factor-1 (SF-1) for treating adrenocortical carcinoma (ACC). SF-1 is highly expressed in ACC and some head and neck and lung squamous carcinomas, with preclinical studies demonstrating OR-449's efficacy in inhibiting tumor growth.

OR-449 is designed to reduce reliance on existing ACC treatments, which have limited success rates. Preclinical toxicology studies have shown no adverse effects, supporting OR-449's advancement into clinical trials for ACC, where options are currently limited.

Orphagen's project aims to complete a Phase 1 clinical trial, exploring dosage and efficacy in adult and pediatric ACC patients. CPRIT funding will support site activation, interim analyses, and manufacturing necessary for the trial's success.

With CPRIT's support, Orphagen will establish its Texas presence, advancing OR-449 as a first-in-class ACC therapy and reinforcing Texas's role in developing rare cancer treatments.

Select Reviewer Comments

"ACC is a rare cancer with severe outcomes in later-stage disease. If this product proves effective, it could provide a significant improvement over the current standard of care for patients with advanced ACC who face limited treatment options."

"OR-449 is a first-in-class inhibitor of SF-1, a novel target for the treatment of ACC... If successful, this drug has the potential to be a breakthrough therapy for both pediatric and adult ACC patients."

"OR-449 has demonstrated considerable preclinical efficacy... The FDA's rare pediatric disease designation for OR-449 and feedback from the pre-IND meeting provide a positive regulatory pathway for advancing this promising candidate."

TTC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Therapeutics Company Award for Product Development Research:

Eisbach Bio for $4,750,000.

No Contingencies

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.

Eisbach Bio's EIS-12656, a novel DDR helicase inhibitor, targets ALC1 to treat homologous recombination-deficient (HRD) tumors, offering a safer alternative to PARP inhibitors. This innovation addresses a significant need, particularly in PARPi-resistant and HRD-positive tumors with brain metastases.

Preclinical studies show EIS-12656's robust safety profile and blood-brain barrier penetrance, making it suitable for monotherapy and combination therapies with cPARPi and other agents. The drug's efficacy in HRD contexts highlights its transformative potential in solid tumor treatment.

Supported by a partnership with MDACC, Eisbach Bio will conduct Phase I/II trials, with CPRIT funding supporting dose expansion. Relocating to Texas, Eisbach will strengthen Texas's role in oncology, leveraging collaborations to drive EIS-12656's clinical success.

CPRIT funding will support Eisbach's transformative approach to HRD tumor therapy, positioning Texas as a hub for innovative cancer treatments while expanding clinical options for HRD patients.

Select Reviewer Comments

"EIS-12656 has the potential to be a game-changing therapy for patients suffering from HRD solid tumors... with significant potential to improve outcomes for those who have developed resistance to PARP inhibitors."

"As a first-in-class allosteric inhibitor of ALC1, EIS-12656 represents a novel approach, targeting HRD tumors with potential broad applicability across multiple cancer types."

"EIS-12656 demonstrated a markedly superior toxicity profile in comparison with currently available therapies targeting DDR pathways, and the FDA's clearance of the IND underscores the strength of the preclinical data."

TDDC

The PDRC recommends that the PIC and Oversight Committee approve a Texas Device and Diagnostics Company Award for Product Development Research:

Curve Biosciences for $11,340,000.

No Contingencies

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.

Curve Biosciences is developing a blood-based assay, the Curve Test, aimed at enhancing early detection of hepatocellular carcinoma (HCC) in high-risk populations. The current standard of care (SOC) for HCC, which includes ultrasound imaging and alpha-fetoprotein testing, detects only 33% of early HCC cases due to challenges in patient compliance and limited sensitivity for small tumors. The Curve Test addresses this gap by using specific biological markers unique to HCC, thus improving early detection accuracy.

The innovation behind the Curve Test is powered by Curve's Whole-Body Tissue Atlas (WBTA), a database of over 400,000 samples from various tissue types, which enables precise identification of HCC-specific biomarkers. By distinguishing HCC markers from unrelated biological signals, the Curve Test can detect early-stage HCC with 84% sensitivity—significantly outperforming current SOC. This improvement could boost the five-year survival rate from 27% to 52%, representing a major advance in patient outcomes and offering substantial cost savings for insurers.

To support commercialization, Curve plans three studies: an 800-patient trial for regulatory clearance, a 2000-patient utility study comparing Curve Test with SOC, and a 3000-patient pilot study to capture ordering behaviors and support broader insurance adoption. These studies aim to solidify Curve Test's role as a superior HCC detection method and to drive widespread insurance coverage.

CPRIT funding will be instrumental in advancing the Curve Test, accelerating Curve's timeline to market and facilitating the company's significant Texas-based operational expansion. The award would also support the establishment of a headquarters, clinical lab, and Texas-based collaborations, positioning Texas as a leader in diagnostic advancements for liver cancer.

Select Reviewer Comments

"The management team is very strong, bringing in high-level people from well-respected institutions like Genentech, GRAIL, and Stanford University. This reviewer has no concerns about the leadership team."

"This proposal contains very strong preliminary data. Specifically, they performed a blinded, multi-site study involving 194 patients that were at high risk for liver cancer, tested using the

Curve assay against a gold standard (MRI), with results showing 95% sensitivity and 96% specificity."

"The market opportunity here appears strong, with a projected market size of over $10B in the U.S. for surveilling high-risk liver disease patients. Interviews with target physicians indicate that 92% are willing to order this new test if it can be reimbursed."

De-Identified Overall Evaluation Scores

Texas Therapeutics Company Awards

Product Development Research Cycle 25.1

Full Application Review

Application ID	Final Overall Evaluation Score
DP250150*	2.1
DP250135*	2.4
DP250159*	2.4
DP250140*	2.6
DP250142*	2.7
Q	3.3
R	3.6
S	3.7
T	4.1

* Recommended for funding.

Texas Therapeutics Company Awards

Product Development Research Cycle 25.1

Final Scores for Preliminary Application Review

CPRIT uses a preliminary application review process to quickly provide an applicant with feedback about whether the proposed project is compatible with the CPRIT portfolio and mission. A panel of experts individually reviewed and scored preliminary applications using the criteria listed in the Request for Applications (RFA). These are the final overall evaluation scores for preliminary applications that were not invited to submit full applications. The review process ends after preliminary review for those applicants not invited to submit a full application.

Application ID	Final Overall Score
Fa	2.2
Fb	2.2
Fc	2.3
Fd	2.3
Fe	2.4
Ff	2.5
Fg	2.8
Fh	3.2
Fi	3.3
Fj	3.3
Fk	3.4

Final Overall Evaluation Scores and Rank Order Scores

October 29, 2024

Dr. David Cummings
CPRIT Oversight Committee Chair
Via email to dcummingsmd@yahoo.com

Ms. Kristen Pauling Doyle
CPRIT Program Integration Committee Chair
Via email to kdoyle@cprit.texas.gov

Dr. Cummings and Ms. Doyle,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 25.1 grant award cycle. The PDRC convened on October 28, 2024, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Curve Biosciences, Marker Therapeutics, Inc., Telos Biotechnology, Metaclipse Therapeutics Corp., Barricade Therapeutics, Corp., Ypsilon Therapeutics, Orphagen Pharmaceuticals, Inc., Eisbach Bio Inc., and Erisyon Inc. The attached table reflects the ranked award recommendation for the nine (9) grant applications. The recommendations contain no contingency.

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

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Council

CPRIT 25.1 Product Development Research
Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Application Title	Organization	Final Overall Score	Recommended Budget
1	DP250157	TDDC	New	Patnaik, R	Clinical Utility Study for the Commercial Launch of a Best-in-Class Liver Cancer Screening Blood Test for High-Risk Liver Disease Patients	Curve Biosciences	1.9	$ 12,600,000
2	DP250150	TTC	New	Vera, J	A Phase 1 Study of Multi-Tumor Associated Antigen Specific T Cells (MT-601) in Patients with Metastatic Pancreatic Cancer following frontline FOLFIRINOX	Marker Therapeutics, Inc.	2.1	$ 10,226,179
3	DP250143	SEED	Resubmission	Sayed, M	TELOVANCE: A Transient Telomere Lengthening Platform Designed to Enhance the Expansion and Efficacy of Human Cell and Gene Therapies	Telos Biotechnology	2.3	$ 2,998,945
4	DP250135	TTC	Resubmission	Pack, C	Personalized Immunotherapy for Recurrent, Resectable Head and Neck Cancer	Metaclipse Therapeutics Corporation	2.4	$ 6,395,245
5	DP250159	TTC	New	Thapar, N	(S)-TASIN-15 Phase 1 Dose Escalation, Optimization & RP2D Determination	Barricade Therapeutics, Corp.	2.4	$ 15,485,443
6	DP250137	SEED	New	Zha, D	Revolutionizing Solid Tumor Therapy with Bispecific TCRm Antibodies Targeting Intracellular Cancer Targets	Ypsilon Therapeutics	2.5	$ 2,997,500
7	DP250140	TTC	New	Thacher, S	A Phase 1 clinical trial of OR-449, a novel oral targeted therapy for pediatric and adult adrenocortical cancer patients	Orphagen Pharmaceuticals, Inc.	2.6	$ 10,917,769
8	DP250142	TTC	Resubmission	Schomburg, A	Eisbach Bio - Clinical Development of the ALC1 DDR inhibitor EIS-12656	Eisbach Bio Inc.	2.7	$ 5,000,000
9	DP250149	SEED	New	Swaminathan, J	Functional assay of immunoproteasome for patient stratification to checkpoint inhibitor therapy using single-molecule protein sequencing	Erisyon, INC	2.8	$ 2,242,852

Cancer Prevention & Research
Institute of Texas

CEO Affidavit
Supporting Information

Prevention
FY 2025—Cycle 1
Cancer Screening and Early Detection

Request for Applications

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA P-25.1-CSD

Cancer Screening and Early Detection

Please also refer to the Instructions for Applicants document

Application Receipt Opening Date: March 7, 2024
Application Receipt Closing Date: June 6, 2024

FY 2025
Fiscal Year Award Period
September 1, 2024-August 31, 2025

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 2/9/2024 RFA release

Rev 3/7/2024 Section 4.4.2 – Goals and Objectives

- Goals and Objectives character limits were increased to 1200 characters each

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

1.1 Prevention Program Priorities

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

Established Principles:

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

CPRIT's Cross-Program Priorities:

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

Prevention Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services
- Assess the CPRIT Prevention Program to identify best practices, use as a quality improvement tool, and guide future program direction

2. FUNDING OPPORTUNITY DESCRIPTION

2.1 Summary

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

This award mechanism seeks to support the delivery of evidence-based clinical services to screen for cancer and precancer in priority populations who do not have adequate access to screening and early detection interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Screening for cancer recurrence or a new primary cancer in the cancer survivor population is supported by this mechanism.

Projects should identify cancers that cause the most burden in the community, have nationally recommended screening methods, and use evidence-based methods to screen for these cancers. Delivery of clinical services is restricted to residents of Texas.

Partnerships with other organizations that can support and leverage resources are strongly encouraged. A coordinated submission of a collaborative partnership program in which all partnershave a substantial role in the proposed project is preferred.

NOTE: The CSD award mechanism will not support cancer prevention/intervention research; projects must be focused on implementing existing evidence-based screening and diagnostic testing in communities. Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).

2.2 Project Objectives

CPRIT seeks to fund projects that will do the following:

- Deliver comprehensive projects comprising all the following: public and/or professional education, outreach, delivery of clinical services, follow-up navigation to diagnosis and into cancer treatment, and system and/or policy improvements.
- Offer effective and efficient systems of delivery of screening services based on the existing body of knowledge about and evidence in ways that far exceed current performance in a given service area.
- Implement policy changes and/or system improvements that are sustainable over time (eg,decrease wait times between positive screen and diagnostic tests and treatment through improved navigation, reminder systems)
- Provide tailored, culturally appropriate outreach and accurate information on early detection and prevention to the public and health care professionals that results in a health impact that can be measured.

2.3 Award Description

The **Cancer Screening and Early Detection** RFA solicits applications for eligible projects up to 5 years in duration that will deliver evidence-based clinical services in cancer screening for breast, cervical, colorectal, liver, and lung cancers according to established and current national guidelines and criteria, inclusive of the screening and early detection of recurring or second primary cancers in the cancer survivor population. Nonmetropolitan (rural) and/or medically underserved populations must be included in the defined service area.

The following are required components of the project:

- **Geographic Area to be Served:** Clinical service delivery to nonmetropolitan/medically underserved area (MUA) counties must be included in the defined service area. Rural and MUA counties may be identified via web-based tools from the US Department of Health

and Human Services. Service to urban/nonmedically underserved counties is allowable if the project proposes to also serve nonmetropolitan/medicallyunderserved counties.

- **Comprehensive Projects:** Comprehensive projects include a continuum of services and systems and policy changes and comprise all the following: Public and professional education and training, outreach, delivery of screening and diagnostic services, follow-up navigation into treatment services for those diagnosed with cancer and precancer, data collection and tracking, and systems improvement.
- **Evidence Based:** CPRIT's secondary prevention grants are intended to fund effective and efficient systems of delivery of early detection services based on the existing body of knowledge about and evidence for screening for both primary and secondary cancers in ways that far exceed current performance in a given service area. The provision of clinical services, including rescreening at the appropriate interval, must comply with established and current national guidelines (eg, US Preventive Services Task Force [USPSTF], American Cancer Society [ACS]).

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

  The National Comprehensive Cancer Network and the ACS have developed consensus-based comprehensive survivorship care guidelines to provide direction on managing the potential physical and psychosocial long-term impact of cancer/associated treatment and subsequent surveillance for recurrence and screening for second primary cancers for projects focusing on survivor care.

- **Clinical Service and Community Partner Networks:** If applicable to the proposed project, applicants are encouraged to coordinate and describe a collaboration of clinical service providers and community partners that can deliver outreach, education, clinical, and navigation services to the most counties and the most people possible in a selected

service region. Applicants should consider providing financial assistance to service providers for navigation services. Partnerships with other organizations that can support and leverage resources (eg, community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations) are encouraged. Letters of commitment or memoranda of understanding describing their specific role in the partnership will strengthen the application.

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

This mechanism will fund case management/patient navigation to screening, to diagnostic testing, and into treatment. Applicants must ensure that diagnostic testing for those with an abnormal screening exam and navigation into treatment services for patients with precancer or cancers that are detected as a result of the project are provided and must describe the process for ensuring diagnostic and navigation into treatment services.

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

CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based clinical services, changes in provider practice, systems changes, and cost-effectiveness. Applicants must demonstrate how these outcomes will ultimately impact incidence mortality, morbidity, and disparities.

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

- Projects focused solely on metropolitan counties that are not medically underserved.

- **Projects focused solely on primary cancer prevention services.** These applicants should apply under the Primary Prevention of Cancer RFA. Primary prevention services are allowable under this RFA if combined with cancer screening/early detection services (eg, hepatitis B vaccination with hepatitis C screening, HPV vaccination with cervical cancer screening).
- Projects focusing solely on systems and/or policy change or solely on education and/or outreach that do not include the navigation to and delivery of cancer screening and early detection services.
- **Projects focusing on screening the general population for genetic disposition to cancer.**
- **Projects focusing solely on case management/patient navigation services.** Case management/patient navigation services must be paired with the delivery of a clinical cancer screening service and reported to CPRIT, including those services delivered by another provider. Furthermore, while navigation into treatment of cancer is required when cancer is discovered through a CPRIT-funded project, applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.
- Clinical tests/services proposed as part of the project that do not comply with established and current national guidelines and criteria, have not yet been approved by the FDA, and/or have not been recommended by the USPSTF due to lack of evidence available to draw reliable conclusions about benefits and harms of the tests. These include, but are not limited to, breast self-exams, clinical breast exams, HPV self-sampling tests, and prostate-specific antigen (PSA) tests.
- **Prevention/intervention research projects.** Projects must be focused on implementing existing evidence-based screening and diagnostic testing in communities. Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).
- Resources for the treatment of cancer or viral treatment for hepatitis.

2.4 Priorities

Types of Cancer: Applications addressing any cancer type(s) that can be prevented or detected early (breast, cervix, colorectal, liver, lung), are recommended by the USPSTF, and are responsive to this RFA will be considered for funding. See section 2.5 for specific areas of emphasis. All services must comply with established and current national guidelines.

Lung cancer screening projects must also meet the Centers for Medicare and Medicaid Services (CMS) eligibility criteria for radiologists and facilities. CMS also requires delivery of smoking cessation counseling if low-dose computed tomography screening is offered. Shared decision-making about the eligibility, risks, and benefits of annual lung cancer screening between the health care provider and patient is required.

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

1) **Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.**

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

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

The age of the priority population and frequency of screening/rescreening for provision of clinical services described in the application must comply with established and current national guidelines (eg, USPSTF, ACS). Clearly state the national guideline that will be followed.

2) **Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.**

While disparities and needs exist across the state, CPRIT will also prioritize applications proposing to serve geographic areas of the state disproportionately affected by cancer incidence,

mortality, or cancer risk prevalence. For this RFA, projects must propose to serve nonmetropolitan and/or medically underresourced areas of the state. In addition, projects addressing areas of emphasis (see section 2.5) will receive priority consideration.

Geographic and Population Balance in Current CPRIT portfolio

At the programmatic level of review conducted by the PRC (section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see https://www.cprit.texas.gov/our-programs/prevention/portfolio-maps and https://www.cprit.texas.gov/grants-funded?search=prevention).

2.5 Specific Areas of Emphasis

CPRIT has identified the following areas of emphasis for this cycle of awards.

Secondary Prevention – Screening and Early Detection Services
Breast Cancer
• Decreasing disparities in mortality rates of breast cancer in racial/ethnic populations. The mortality rate is significantly higher in Black women than in other populations.
• Increasing screening/detection rates in MUAs of the state.
Cervical Cancer
• Decreasing disparities in incidence and mortality rates of cervical cancer in racial/ethnic populations. Hispanic women have the highest incidence rates while Black women have the highest mortality rates.
• Increasing screening/detection rates in MUAs of the state.
Colorectal Cancer
• Decreasing disparities in incidence and mortality rates of colorectal cancer in racial/ethnic populations. Blacks have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics.
• Increasing screening/detection rates in Public Health Region (PHR) 1, 2, 4, 5, and 9, where the highest rates of cancer incidence are found. Mortality rates are highest in PHR 2 and 9. • Decreasing incidence and mortality rates in nonmetropolitan counties. Incidence and mortality rates are higher in nonmetropolitan counties compared with metropolitan counties.
Liver Cancer
• Screening for hepatitis C virus infection in populations at high risk of infection.
• Increasing screening rates in PHR 1, 8, 9, 10, and 11. Incidence and mortality rates are highest in PHR 10 and 11.

Lung Cancer
• Decreasing disparities in incidence and mortality rates of lung cancer in racial/ethnic populations. Blacks have higher mortality rates than Hispanics and non-Hispanic Whites. • Increasing screening/early detection rates in PHR 2, 3, 4, 5, and 7 where the highest rates of cancer incidence are found. Mortality rates are highest in PHR 4 and 5.

See the Texas Cancer Registry for data on cancer incidence rates in Texas (https://www.cancer-rates.info/tx/).

2.6 Outcome Metrics

Applicants are required to clearly describe their assessment and evaluation methodology. The applicant is required to describe final outcome measures for the project. Output measures that are associated with the final outcome measures should be identified only in the project plan and will serve as a measure of program effectiveness. Planned policy or system changes/improvements should be identified and the plan for qualitative analysis described. **Baseline data for each measure proposed are required**. In addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to establish a baseline.

Reporting Requirements

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

If someone other than the PD will enter information in the progress reports, they must be named as an Alternate Submitter in CARS. The Alternate Submitter is an application contact designated by the PD to complete PD tasks in CARS and/or the grants management system.

If clinical services are being paid for and provided by others, the applicant is required to report on the number of clinical services and outcomes (eg, cancers detected) that are delivered to the people navigated by the program.

2.7 Funding Information

The total amount of funding that applicants may request is dependent on the project type. Use the table below to determine the maximum amount of funding and the maximum number of years that may be requested.

Project Type	Maximum Amount of Total Funding	Maximum Duration
New Project	$1.5 million	3 years
Initial Expansion Project	$2 million	3 years
Maintenance Expansion Project	$2.5 million	5 years

Expansion projects require **significant expansion** in the geographic area and/or clinical services provided for the initial expansion, or in the number of clinical services delivered for any subsequent expansion, as described in section 2.10. Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Applicants must ensure that there is access to and navigation into treatment services for patients with precancers or cancers that are detected as a result of the program and must describe access to and navigation into treatment services in their application.

Requests for funds to support construction or renovation or requests to support lobbying will not be approved. Cost sharing for equipment purchases is encouraged. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

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

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

2.8 Eligibility

- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The designated PD will be responsible for the

overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.

- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field and who resides in Texas during the time that the project is conducted.
- The applicant may submit more than 1 application, but each application must be for distinctly different services without overlap in the services provided. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review.
- If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary. Duplicative applications will be administratively withdrawn.
- If the applicant or a partner is an existing Department of State Health Services contractor, CPRIT funds may not be used as a match, and the application must explain how this grant complements or leverages existing state and federal funds.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- An applicant organization is eligible to receive a grant award only if the applicant certifiesthat the applicant organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.

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

2.9 Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. Resubmission applications must include a Resubmission Summary (see section 4.4.10).
- Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

2.10 Expansion Policy

- Expansion grants are intended to fund expansion of currently or previously funded projects that have demonstrated exemplary success, as evidenced by progress reports and project evaluations, and desire to further enhance their impact on priority populations. Detailed descriptions of **results, barriers, outcomes, and impact of the currently or**

previously funded project are required (see outline of Most Recently Funded Project Summary, section 4.4.11).

- Proposed expansion projects should NOT be new projects but should closely follow the intent and core elements of the currently or previously funded project. Established infrastructure/processes are required.
- Fully described prior results of the project upon which the initial or maintenance expansion is based should be provided. These include numbers of screenings, repeat screenings, diagnostics, cancer precursors, cancers detected, measured outcomes, policy/system/environmental changes implemented, and program evaluation results.
- Expansion of current projects into geographic areas not well served by the CPRIT Prevention portfolio (see maps at http:// www.cprit.state.tx.us/our-programs/prevention/portfolio-maps) will receive priority consideration.
- CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area). It is expected that baselines will have already been established and that continued improvement over baseline is demonstrated in the current application. However, in the case of a proposed expansion where no baseline data exist for the priority population, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline. Applicants must demonstrate how these outcomes will ultimately impact cancer incidence, mortality, morbidity, or quality of life.
- CPRIT also expects that applications for continuation **will not** require startup time, that applicants can demonstrate that they have overcome barriers encountered, and that applicants have identified **lasting systems changes** that improve results, efficiency, and sustainability. Leveraging of resources and plans for dissemination are expected and should be well described.

Requirements for Initial and Maintenance Expansion Projects

- **Initial Expansion:** For the first expansion application, eligible applicants should propose to expand their programs to include additional types of prevention clinical services or to expand current clinical services into additional counties. Rescreening of individuals served by the prior project should be included. In either case, the expansion must include

the delivery of services to nonmetropolitan (rural) and/or medically underserved counties in the state. These may be identified via web-based tools from the Texas Department of State Health Services and US Department of Health and Human Services.

- **Maintenance Expansion:** For a subsequent expansion, additional clinical services and/or expansion to additional counties is optional; however, the counties and the practices offered in the first expansion should not be decreased. The number of services delivered during the maintenance expansion must be increased substantially such that the cost per clinical service is similar to the initial expansion if no further geographic or preventive service expansion is proposed. Rescreening of individuals served by the prior project should be included.

3. KEY DATES

RFA release	February 9, 2024
Online application opens	March 7, 2024, 7 AM central time
Application due	June 6, 2024, 4 PM central time
Application review	June-September 2024
Award notification	November 2024
Anticipated start date	December 1, 2024

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

4. APPLICATION SUBMISSION GUIDELINES

4.1 *Instructions for Applicants* document

It is **imperative** that applicants read the accompanying instructions document for this RFA (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2 Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The PD must create a user account in the system to start and

submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 7, 2024, and must be submitted by 4 PM central time on June 6, 2024. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3 Submission Deadline Extension

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

4.4 Application Components

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

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

4.4.1 Abstract and Significance (5,000 characters)

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

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

- **Need:** Include a description of need in the specific service area. Include rates of incidence, mortality, and screening in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the priority population to be served.

- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project, including the prepopulated navigation into diagnosis and treatment goal; include the estimated overall numbers of clinical services delivered and number of people (public and/or professionals) served.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.4.2 Goals and Objectives (1200 characters each)

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within both the stated Objective **and** the Measure sections (eg, Measure: 1,500 individuals, ages 45 to 75, will be screened for colorectal cancer during the grant period). Applications may be returned for revision if the proposed metric is not included within the Measure section. Refer to the Instructions for Applicants document for details.

One goal with 2 objectives addressing navigation into diagnosis and into treatment is required for all proposals and will be prepopulated into the application. This goal is not modifiable by the applicant. Applicants may **ADD** a maximum of 3 **additional** goals with up to 3 outcome objectives each. Projects will be evaluated annually on progress toward **all** outcome goals and objectives. See appendix B for instructions on writing outcome goals and objectives.

A baseline and method(s) of measurement are required for each objective, including the prepopulated goal. Provide both raw numbers and percent changes for the baseline and target (eg, provide 200 clinical services, a 100% increase from a baseline of 100). If a baseline has not been defined, applicants are required to explain plans to establish baseline and describe method(s) of measurement. Note that character limits are inclusive of all words in each text box, including provided headings.

4.4.3 Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3 and Months 1, 2, 3, etc, as applicable (eg, Year 1, Months 3-5). **Do NOT** refer to specific months or years (eg, not May 2024). Month 1 (as opposed to June 1, 2024) is the first full month of the grant award.

4.4.4 Project Plan (12 pages; fewer pages permissible)

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

Background: Briefly present the rationale behind the proposed services, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the priority population. Describe the race, ethnicity, age, and other defining characteristics of the population to be served.

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the priority population and proposed service area are required where applicable.

Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are encouraged.

Goals and Objectives: Process objectives should be included in the project plan, including the process of achieving the prepopulated navigation into diagnosis and treatment goal. Outcome goals and objectives will be entered in separate fields in CARS. However, if desired, outcome goals and objectives may be fully repeated or briefly summarized here. See appendix B for instructions on writing goals and objectives.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services, as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary.

It is important to distinguish between Texas counties where the project proposes to deliver services and counties of residence of population served (see appendix A for definitions and *Instructions for Applicants*). Only counties with service delivery should be listed in the Geographic Area to be Served section of the application. Projecting counties of residence of population served is not required but may be described in the project plan.

Clearly demonstrate the ability to provide the proposed service(s) and describe how results will be improved over baseline and the ability to reach the priority population. Describe the method(s) that will be used to recall for appropriate rescreening those individuals who have been screened through this or the previous project.

If clinical services are being paid for and provided by others, the applicant must explain and report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program. Applicants must also clearly describe **access to and navigation into treatment services** should precancer or cancer be detected and assurances that the treatment services will be covered for those who are uninsured or underinsured. Include how and by whom any positive screening results will be delivered to a program participant.

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

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing health programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. The applicant should demonstrate how the organizational environment will contribute to a successful project. If equipment or physical resources are required to carry

out the project, the applicant should describe the availability of these resources and the organizational capacity to use equipment. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

Project Maintenance and Sustainability: CPRIT acknowledges that full maintenance and sustainability of projects when CPRIT funding ends may not be feasible, especially in cases involving the delivery of clinical services. However, it is important to consider sustainability early in the life cycle of a project, particularly regarding organizational characteristics and processes that are modifiable.

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

It is expected that steps toward building capacity for the program will be taken and plans for such should be described in the application. The applicant should describe the factors that will contribute to the organization's capacity to facilitate sustainability.

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

While passive dissemination methods are common (eg, publications, presentations at professional meetings), plans should include some active dissemination methods (eg, meetings with stakeholders, blogs, social media). Applicants should describe their dissemination plans. The plans should include the kinds of audiences to be targeted and methods for reaching the

targeted audiences. See Dissemination Resources for additional information on dissemination methods.

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

4.4.5 People Reached (Indirect Contact)

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

4.4.6 Number of Unique People Served (Direct Contact)

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

4.4.7 Number of Services Delivered (Direct Contact)

Provide the estimated overall number of services directly delivered to members of the public and to professionals by the funded project. Each individual service should be counted, regardless of the number of services 1 person receives. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimate provided. Refer to appendix A for definitions.

4.4.8 Number of Clinical Services Delivered

Provide the estimated overall number of clinical services directly delivered to members of the public by the funded project. Each individual clinical service should be counted, regardless of the number of services 1 person receives. Separately itemize the clinical services, with estimates, that led to the calculation of the overall estimate provided. Refer to appendix A for definitions.

4.4.9 References

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

4.4.10 Resubmission Summary

Resubmission applications must include a Resubmission Summary. Use the template provided on the CARS website (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed.

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

4.4.11 Most Recently Funded Relevant CPRIT Prevention Project Summary (only if applicable) (3 pages)

Upload a summary that outlines the progress made with the applicant's most recently funded relevant CPRIT Prevention Award. Applicants must describe results and outcomes of the most recently funded award and demonstrate why further funding is warranted.

Please note that a different set of reviewers from those assigned to the previously funded application may evaluate this application. Applicants should make it easy for reviewers to comparethe most recently funded project with the proposed project.

In the description, include the following:

- Describe the evidence-based intervention, its purpose, and how it was implemented in the priority population. Describe any adaptations made for the population served.
- List approved goals and objectives of the most recently funded grant.
- For each objective, provide milestones/target dates and target metrics as compared to actual completion dates and metrics.

- Include a discussion of objectives not fully met. Explain any barriers encountered and strategies used to overcome these.
- For the most recently funded project, describe major activities; significant results, including major findings, developments, or conclusions (both positive and negative); and key outcomes.
- Describe steps taken toward sustainability for components of the project. Fully describe systems or policy improvements and enhancements.
- Describe how project results were disseminated or plans for future dissemination of results.

4.4.12 CPRIT Grants Summary

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

4.4.13 Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in section 2.7 will be administratively withdrawn.

Clearly describe any organizational cost sharing or pro bono contributions related to this project, as well as any attempts made or successes to secure other state/federal funds.

- **Average Cost per Person:** The average cost per person will be automatically calculated from the total cost of the project divided by the total number of unique people served (refer to appendix A).
- **Average Cost per Service:** The average cost per service will be automatically calculated from the total cost of the project divided by the total number of services delivered (refer to appendix A). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.

- **Average Cost per Clinical Service:** The average cost per clinical service will be automatically calculated from the total cost of the project divided by the total number of clinical services delivered (refer to appendix A).
- **Personnel:** The individual salary cap for CPRIT awards is $225,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference. Meals are not reimbursable for trips that do not include an overnight stay.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.
- **Supplies:** Includes medical supplies, medications, office supplies, patient education supplies, computer software/Wi-Fi cards, laptops and iPads, consumable items.
- **Services Costs:**
    - CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested. If clinical services are being paid for and provided by others, the applicant is required to explain and report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program.
    - CPRIT does not allow recovery of any costs for services not related to cancer (eg, health physicals, HIV testing) other than those required prior to the clinical services proposed in the project.
    - CPRIT does not allow recovery of costs related to tests that have not been recommended by the USPSTF. In several cases (eg, breast self-exams, clinical breast exams, PSA tests), the Task Force has concluded there is not enough evidence available to draw reliable conclusions about the additional benefits and harms of these tests. (See https://www.uspreventiveservicestaskforce.org/)

- **Other:**
  - **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is $25.
  - Includes Internet services, telephone expenses, printing expenses/copying services, postage, client incentives, service agreements, publication fees.
  - **Conference/Seminar Registration Fees (not associated with travel):** Conference and seminar registration fees paid prior to travel should be reported in the "Other" category.
- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Indirect costs reimbursed to subcontractors count toward the total allowable indirect costs. Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.14 Current and Pending Support and Sources of Funding

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

4.4.15 Biographical Sketches

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

- Use the Co-PD Biographical Sketch section ONLY if a Co-PD has been identified.
- The evaluation professional must provide a biographical sketch in the Evaluation Professional Biographical Sketch section.

- Up to 3 additional biographical sketches for key personnel may be provided in the Key Personnel Biographical Sketches section.

Each biographical sketch must not exceed 5 pages and should use either the "Prevention Programs:Biographical Sketch" template provided on the CARS (https://CPRITGrants.org) or the NIH Biographical Sketch format. Only biographical sketches will be accepted; do not submit resumes and/or CVs. If a position is not yet filled, please upload a job description.

4.4.16 Personnel and Collaborating Organizations

List ALL paid and unpaid personnel working on the proposed project, including those listed on the Personnel Level of Effort form, as well as partners, collaborators, and anyone listed under the Current & Pending Support section.

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

4.4.17 Letters of Commitment (10 pages)

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

5. APPLICATION REVIEW

5.1 Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the PRC. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the PRC and recommended for funding based oncomparisons with applications from all of the review panels and programmatic priorities.

Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The peer review scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be

given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by the PRC 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 andeligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

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

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

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

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or a PRC 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 when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2 Review Criteria

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

5.2.1 Primary Evaluation Criteria

Impact

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

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?

- Are the overall program approach, strategy, and design clearly described and supported by established theory and practice? Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Has the applicant proposed policy changes and/or system improvements?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including follow-up for abnormal results and access to and navigation into treatment?
- Does the program leverage partners and resources to maximize the reach of the services proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

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

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services?
- Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to design, implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?
- Does the applicant describe the program's organizational capacity for sustainability?
- Does the applicant describe steps that will be taken toward building internal capacity and partnerships?
- Does the applicant describe a plan for systems changes that are sustainable over time (eg, improve results, provider practice, efficiency, cost-effectiveness)?

5.2.2 Secondary Evaluation Criteria

Budget

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

Dissemination and Replication

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

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award

contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

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

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

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

7. CONTACT INFORMATION

7.1 Helpdesk

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

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

7.2 Program Questions

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

Tel: 512-626-2358
Email: prevention@cprit.texas.gov
Website: www.cprit.texas.gov

8. RESOURCES

8.1 General Resources

- The Texas Cancer Registry. https://www.dshs.texas.gov/tcr or contact the Texas Cancer Registry at the Department of State Health Services.
- The Community Guide. https://www.thecommunityguide.org/
- Evidence-Based Cancer Control Programs (EBCCP). https://ebccp.cancercontrol.cancer.gov/
- Guide to Clinical Preventive Services: Recommendations of the US Preventive ServicesTask Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Program Sustainability Assessment Tool, copyright 2012, Washington University, St Louis, MO. https://www.sustaintool.org/about-us/
- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs. http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. https://www.cdc.gov/os/integrity/docs/cdc-policy- distinguishing-public-health-research-nonresearch.pdf
- Centers for Disease Control and Prevention. Answering Parents' Questions About HPV Vaccination. https://www.cdc.gov/hpv/hcp/answering-questions.html

8.2 Dissemination Resources

- Brownson, RC, Colditz GA, and Proctor, EK. (Editors). *Dissemination and Implementation Research in Health: Translating Science to Practice.* Oxford University Press, March 2012

- Getting the Word Out: New Approaches for Disseminating Public Health Science. Brownson, RC; Eyler, AA; Harris, JK; Moore, JB; Tabak, RG. *Journal of Public Health Management & Practice.* 2018;24(2):102-111. https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out__New_Approaches_for.4.aspx
- "There is no money in community dissemination": A mixed methods analysis of researcher dissemination-as-usual. Uphold, HS; Drahota, A; Bustos, TE; Crawford, MK; Buchalski, Z. *Journal of Clinical and Translational Science*. 2022;6(1):e105, 1-10. doi: 10.1017/cts.2022.437.
- Training researchers in dissemination of study results to research participants and communities. Cunningham-Erves, J; Stewart, E; Duke, J; Akohoue, SA; Rowen, N; Lee, O; Miller, ST. *Translational Behavioral Medicine*. 2021;11(7):1411-1419. doi: 10.1093/tbm/ibab023.
- Dissemination in Extension: Health Specialists' Information Sources and Channels for Health Promotion Programming. Strayer 3rd, TE; Balis, LE; Ramalingam, NS; Harden, SM. *International Journal of Environmental Research and Public Health*. 2022;19(24):16673-16685. doi: 10.3390/ijerph192416673

9. REFERENCES

- Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services. https://www.cancer-rates.info/tx/

APPENDIX A: KEY TERMS

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

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

be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project).

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

APPENDIX B: WRITING GOALS AND OBJECTIVES

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within **both** the stated Objective and the Measure sections (eg, Measure: 2,000 individuals, ages 9-12, will initiate HPV vaccination during the grant period).

One goal with 2 objectives addressing navigation into diagnosis and into treatment is required for all proposals and will be prepopulated into the application. This goal is not modifiable by the applicant. As with other proposed goals and objectives, the applicant is expected to explain plans to establish a baseline and describe method(s) of measurement, if a baseline is not defined.

Applicants may add a maximum of 3 additional goals with 3 outcome objectives each.

Projects will be evaluated annually onprogress toward **outcome** goals and objectives.

The following has been adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604:

Develop well-defined goals and objectives.

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

Goals should be:

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

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

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)
    - Example: 115 uninsured individuals age 50 and older will complete colorectal cancer screening by March 31, 2018.

- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective
    - Example: How many screened at an event? How many completed pre/post assessment?
- Achievable – not only are the objectives themselves possible, it is likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved
- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

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

There are 2 types of objectives:

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

There are 3 levels of objectives:

- Community-level – objectives measure the planned community change
- Program impact – objectives measure the impact the program will have on a specific group of people
- Individual – objectives measures participant changes resulting from a specific program, using these factors:
    - Knowledge – understanding (know screening guidelines; recall the number to call for screening)
    - Attitudes – feeling about something (will consider secondhand smoke dangerous; believe eating 5 or more fruits and vegetable is important)
    - Skills – the ability to do something (complete fecal occult blood test)

- Intentions – regarding plan for future behavior (will agree to talk to the doctor, will plan to schedule a Pap test)
- Behaviors (past or current) – to act in a particular way (will exercise 30+ minutes a day, will have a mammogram)

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

Summary Table

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

Third-Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Prevention Panel-1_Day 1 (25.1_PRV_PP-1)
Observation Report

Report No.	2024-09-10 25.1_PRV_PP-1
Program Name:	Prevention
Panel Name:	25.1 Prevention Panel-1_Day 1 (25.1 _PRV_PP-1)
Panel Date:	September 10, 2024
Report Date:	September 16, 2024

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 25.1 Prevention Panel-1_Day 1 (25.1_PRV_PP-1) meeting. The meeting was chaired by Nancy Lee and conducted via videoconference on September 10, 2024.

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) application were discussed and eight (8) applications were not discussed
- Panelists: One (1) panel chair, twelve (12) reviewers, and three (3) advocate reviewers
- Oversight Committee Members: One (1)
- 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 four (4) Conflicts of Interest (COI) 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.

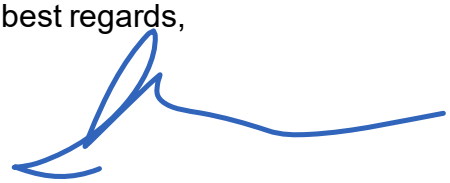
CONCLUSION

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, CRMA, 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) 25.1 Prevention Peer Review Day 2 (25.1_PRV_PP-1_Day 2) Observation Report

Report No.	2024-09-11 25.1_PRV_PP-1 Day 2
Program Name:	Prevention
Panel Name:	25.1 Prevention Peer Review Day 2 (25.1 _PRV_PP-1 Day 2)
Panel Date:	September 11, 2024
Report Date:	September 16, 2024

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 25.1 Prevention Peer Review Day 2 (25.1_PRV_PP-1 Day 2) meeting. The meeting was chaired by Nancy Lee and conducted via videoconference on September 11, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and eighteen (18) applications were not discussed
- Panelists: One (1) panel chair, eleven (11) expert reviewers, and three (3) 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: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) Conflicts of Interest (COI) 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.

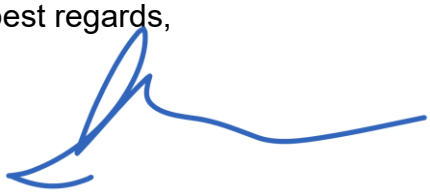
CONCLUSION

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, CRMA, 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)
25.1 Prevention Review Council Programmatic Review
(25.1_PRV_PRC)
Observation Report

Report No.	2024-10-18 25.1_PRV_PRC
Program Name:	Prevention
Panel Name:	25.1 Prevention Review Council Programmatic Review (25.1_PRV_PRC)
Panel Date:	October 18, 2024
Report Date:	October 22, 2024

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 25.1 Prevention Review Council Programmatic Review (25.1_PRV_PRC) meeting. The meeting was chaired by Stephen Wyatt and conducted via videoconference on October 18, 2024.

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 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 eight (8) applications were not discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were 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, CRMA, 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 Prevention Cycle 25.1

Awards Announced at the November 20, 2024, Oversight Committee Meeting

The following table lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention cycle 25.1 include those received in response to the following Requests for Applications: *Cancer Screening and Early Detection; Dissemination of CPRIT-Funded Cancer Control Interventions;* and *Primary Prevention of Cancer*.

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:			
PP250004	Minnix, Jennifer	The University of Texas M.D. Anderson Cancer Center	Mahoney, Martin
Applications not considered by the PIC or Oversight Committee:			
PP250017	Strong, Larkin	The University of Texas M.D. Anderson Cancer Center	Thomson, Cynthia
PP250041	Lapiz-Bluhm, Maria Danet	The University of Texas Health Science Center at San Antonio	Moreno, Patricia
PP250045	Chen, Lei-Shih	Texas A&M University System Health Science Center	Tseng, Tung-Sung

De-Identified Overall Evaluation Scores

Cancer Screening and Early Detection

Prevention Cycle 25.1

Application ID	Final Overall Evaluation Score
PP250006*	2.7
PP250019*	3.1
PP250046*	3.6
PP250004*	3.7
PP250009*	3.8
PP250005*	4.2
A	4.3
B	4.4
C	4.8
D	4.9
E	5.0
F	6.3
G	7.3

* Recommended for funding.

Final Overall Evaluation Scores and Rank Order Scores

Dr. David Cummings
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dcummingsmd@yahoo.com

Kristen Doyle
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to kdoyle@cprit.texas.gov

Dear Dr. Cummings and Ms. Doyle,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for the FY2025 Cycle 1 Cancer Screening and Early Detection (CSD), Primary Prevention of Cancer (PPC), and Dissemination of CPRIT-Funded Cancer Control Interventions (DI) grant awards.

The PRC met on October 18, 2024, to consider the applications recommended by the peer review panel following their September 10 -11, 2024, meeting. The PRC recommends 8 projects totaling $13,446,501.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The average score for recommended applications ranges from 2.7 to 4.2, with an average score of 3.54. The PRC made no changes to the goals, project objectives, or timelines of the applications.

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

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

Attachment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cycle 25.1 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP250006	CSD	Expansion of Cancer Screening and Early Detection Services to Rural & Medically Underserved Communities	Duckworth, Jessica	The Rose	2.7	1	$2,500,000
PP250019	CSD	Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas	Argenbright, Keith	The University of Texas Southwestern Medical Center	3.1	2	$1,499,243
PP250016	PPC	Screening and treatment for unhealthy alcohol use for cancer prevention in Central Texas – 2	Calderon-Mora, Jessica	The University of Texas at Austin	3.4	3	$1,000,000
PP250046	CSD	The Houston Prevenir, Ayudar, Poder (PAP) Project	Zamorano, Abigail	The University of Texas Health Science Center at Houston	3.6	4	$1,499,997
PP250004	CSD	A Virtual, Centralized Lung Cancer Screening Program for Northeast Texas	Minnix, Jennifer	The University of Texas M. D. Anderson Cancer Center	3.7	5	$1,497,342
PP250009	CSD	The Central Texas Colorectal Cancer Screening Program (CTX-CCSP)	Shokar, Navkiran	The University of Texas at Austin	3.8	6	$2,500,000
PP250018	DI	Texas Comprehensive Access & Resources for Early Lung Cancer Prevention (TEX-CARE)	Zoorob, Roger	Baylor College of Medicine	3.8	7	$449,929
PP250005	CSD	Project 80% Colorectal Cancer Screening Program	Foxhall, Lewis	The University of Texas M. D. Anderson Cancer Center	4.2	8	$2,499,990

CSD: Cancer Screening and Early Detection
PPC: Primary Prevention of Cancer
DI: Dissemination of CPRIT-Funded Cancer Control Interventions

Cancer Prevention & Research
Institute of Texas

CEO Affidavit
Supporting Information

Prevention
FY 2025—Cycle 1
Dissemination of CPRIT-Funded Cancer Control Interventions

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA P-25.1-DI

Dissemination of CPRIT-Funded Cancer Control Interventions

Please also refer to the Instructions for Applicants document

Application Receipt Opening Date: March 7,2024

Application Receipt Closing Date: June 6, 2024

FY 2025

Fiscal Year Award Period

September 1, 2024-August 31, 2025

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 2/9/2024 RFA release

Rev 3/7/2024 Section 4.4.2 – Goals and Objectives

- Goals and Objectives character limits were increased to 1200 characters each

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

1.1 Prevention Program Priorities

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

Established Principles

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

Prevention Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services

- Assess the CPRIT Prevention Program to identify best practices, use as a quality improvement tool, and guide future program direction

2. FUNDING OPPORTUNITY DESCRIPTION

2.1 Summary

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

The **Dissemination of CPRIT-Funded Cancer Control Interventions (DI)** award mechanism seeks to fund programs that facilitate the sharing and uptake of successful CPRIT Prevention Program-supported projects, results, and products through their dissemination and implementation across Texas. **This award mechanism is open only to completed CPRIT Prevention Program-funded projects that have ended within the last 3 years or to ongoing expansion projects. A DI application may not be submitted while the original preventive service project is ongoing.** Applicants may request any amount of funding up to a maximum of $450,000 in total funding over a maximum of 36 months. Up to 2 DI awards are allowed for each previously funded CPRIT Prevention Program project.

The proposed program should describe and package strategies or approaches for dissemination to other partners, settings, and populations in the state. The proposed program would introduce, modify, and implement previously funded CPRIT evidence-based cancer prevention and control interventions that have been shown to be successful in their initial CPRIT-funded programs. To be eligible, the applicant should be in a position to develop 1 or more “products” based on the results of a previously CPRIT-funded intervention project. A “product” refers to something that will have real-world impact in the prevention of cancers. An example of a “product” could be a decision support aid, a toolkit, an educational curriculum, data collection tool, etc. Of particular interest is the dissemination of “products” that address the unique challenges to program implementation in

resource-limited settings, particularly in nonmetropolitan and medically underserved areas of the state.

The proposed project application should outline the partner organizations, communities, etc, that would be the recipients for the packaged strategies/products and how they would assist these recipients in preparing to implement the intervention and/or preparing to apply for grant funding, if needed or appropriate.

The project application should include 2 or more ACTIVE dissemination strategies. The **Dissemination and Implementation Models in Health** website defines active and passive dissemination strategies as follows: "Dissemination strategies describe mechanisms and approaches that are used to communicate and spread information about interventions to targeted users. Dissemination strategies are concerned with the packaging of the information about the intervention and the communication channels that are used to reach potential target audiences. **Passive dissemination** strategies are largely ineffective and include mass mailings, publication of information including practice guidelines, and untargeted presentations to heterogeneous groups. **Active dissemination** strategies include hands on technical assistance, replication guides, point-of-decision prompts for use, and mass media campaigns. It is consistently stated in the literature that dissemination strategies are necessary but not sufficient to ensure wide-spread use of an intervention."

2.2 Project Objectives

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

- Dissemination of intervention implementation resources to public health professionals, health care practitioners, health planners, policymakers, and advocacy groups;
- Dissemination of plans, products, materials, and other resources about an intervention that would provide recipients with the strategies necessary to implement in other settings/systems (eg, quality improvement strategies in a health care system, changes in standards of care);
- Dissemination or scaling up of best practices (infrastructure and project resources) and evidence-based interventions for implementation (eg, implementation guides).

2.3 Award Description

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

Applicants to this RFA should outline specific implementation strategies they will utilize with targeted recipients to replicate or adapt projects to other settings or populations. Implementation strategies are described as the processes, activities, and resources that are used to integrate interventions into usual settings. Core implementation components can be staff selection, preservice and in-service training, ongoing consultation and coaching, staff and program evaluation, and systems interventions. (See https://dissemination-implementation.org/)

This award will support both passive and active dissemination strategies but must include 2 or more active dissemination strategies. This award will also support implementation strategies in the form of technical assistance, coaching, and consultation within the time period of the grant. CPRIT recognizes that there are limits to the amount of technical assistance or coaching that can be accomplished within the grant period; however, priority will be given to those projects that identify and assist potential target partners/audiences in preparing to implement the intervention and/or preparing to apply for grant funding. Examples of active dissemination strategies follow.

Tools/Models

- Toolkits with materials, sample policies, and procedures for spread of CPRIT-funded programs.
- Interactive websites that provide target audiences with key information on how to implement CPRIT-related interventions.

Modes of Dissemination

- Approaches for dissemination of project strategies/resources via nontraditional channels (eg, social media).

- Creative, user-friendly summaries—short issue or policy briefs that tell a story for local decisionmakers based on CPRIT project findings.
- Infographics that tell a story in creative and engaging ways.
- Brief, user-friendly case studies and stories from program developers and recipients to illustrate key issues.

Implementation Guides

- Targeted communication materials emphasizing how to disseminate project components to different populations, systems, and settings.
- Step-by-step implementation guides that describe how to translate an evidence-based intervention/program to broader settings. These would include guidelines for retaining core elements of the interventions or programs while offering suggested adaptations for elements that would enhance the adoption and sustainability of the programs in different populations, settings, or circumstances. (See Pathways Community HUB Manual: https:www//ahrq.gov/innovations/hub/index.html).

Training/Technical Assistance

- Provision of training and technical assistance to guide target partners/audiences in developing their plans to adapt, refine, and implement their projects.

In addition, target partners/audiences should be provided a discussion of barriers to dissemination; a description of personnel and necessary resources to overcome barriers to implementation of the project; a description of expected outcomes; evaluation strategies with a sample evaluation plan; any project-specific platforms; and suggestions or ideas for project sustainability.

A priority for this RFA is the dissemination of resources and products to audiences other than researchers. Applicants should consider audience segmentation as outlined by Slater and colleagues. Some examples of potential partners/audiences as dissemination recipients are health departments, community-based organizations, and health systems. To facilitate this dissemination, audience segmentation is a strategy based on identifying subgroups within a broader target audience to disseminate more tailored messaging resulting in greater uptake of innovations. As an example, below are relevant characteristics, possible messages, and channels that should be taken into account for public health practitioners, clinical practitioners, and policymakers.

Segment	Relevant Characteristics	Messages	Channels
Public health practitioners	• High commitment to health • Wide range of professional backgrounds • Access to summaries of evidence but often not the original research • Time urgency	• Make a difference in society • Improve health equity • Enhance resources	• Leadership meetings • Professional associations • Brief summaries of evidence
Clinical practitioners	• High commitment to health • Narrow range of professional backgrounds • Time urgency	• Improve patient care • Improve health equity	• Journal articles • Professional associations • Professional conferences • Brief summaries of evidence
Policymakers	• Variable commitment to health (often limited knowledge across many issues) • Wide range of professional backgrounds • Short-term horizon for outcomes	• Serve constituents • Create return on investment • Get reelected	• Real-world stories • Brief summaries of evidence • Delivery of messages by opinion leaders

The applicant should develop and implement a step-by-step dissemination plan that includes (1) an introduction; (2) data showing the effectiveness of the underlying intervention (to justify dissemination); (3) relevance to priority populations and settings for dissemination; (4) target partners or strategies they will utilize to identify these critical partners; (5) dissemination framework and methods; (6) approaches for retaining core elements of the interventions or programs while offering suggested adaptations that would enhance the adoption and sustainability of the programs in different populations, settings, or circumstances; (7) procedures to assess dissemination effectiveness (evaluation plan); and (8) options/plans to help sustain effective dissemination approaches beyond the funding period.

Within the evaluation plan (#6 in the paragraph above and section 4.4.4), the applicant should state the overall goal and clear and time-bound objectives of the evaluation, describe appropriate evaluation methods, and describe key variables to be measured (eg, awareness, knowledge, motivation to act, changes in practice). Measures (outcomes) may be short term, medium term, and long term. Long-term measures may be outside the scope of the 3-year funding period. Examples of dissemination outcomes are found in the review by Baumann and colleagues (Baumann et al. *Implement Sci.* Aug 9, 2022;17(1):53. doi:10.1186/s13012-022-01225-4). In addition to the measures, the applicant should specify the evaluation design, sampling and data collection methods, plans for analysis, and as appropriate, steps to maximize the validity and reliability of measures and findings. The applicant is expected to publish the results of the evaluation in a peer-reviewed journal. Materials developed will be placed on the CPRIT website.

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

- Applications to disseminate projects not previously funded by CPRIT's Prevention Program
- Applications to disseminate original (not expansion) projects that are currently funded by CPRIT's Prevention Program
- Projects solely involving prevention/intervention research.

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

2.4 Priorities

Cancer Focus:

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

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services

Priority Populations

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

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

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

2.5 Specific Areas of Emphasis

Applications will be considered that propose dissemination of any previously funded CPRIT Prevention Program project that delivered an evidence-based preventive service that is responsive to this RFA. However, CPRIT has identified the following area of emphasis for this cycle of awards:

- Dissemination of the programs that address the unique challenges to program implementation in resource-limited settings and populations experiencing cancer disparities.

2.6 Outcome Metrics

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

Reporting Requirements

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

If someone other than the Program Director (PD) will enter information in the progress reports, they must be named as an Alternate Submitter in CARS. The Alternate Submitter is an application contact designated by the PD to complete PD tasks in CARS and/or the grants management system.

2.7 Funding Information

Applicants may request any amount of funding up to a maximum of $450,000 in total funding over a maximum of 36 months. Grant funds may be used to pay for salary and benefits, project supplies, equipment, costs for outreach and education, and travel of project personnel to project site(s). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

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

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

2.8 Eligibility

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

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

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

2.9 Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. Resubmission applications must include a Resubmission Summary (see section 4.4.6).
- 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.

3. KEY DATES

RFA release	February 9, 2024
Online application opens	March 7, 2024, 7 AM central time
Application due	June 6, 2024, 4 PM central time
Application review	June-September 2024
Award notification	November 2024
Anticipated start date	December 1, 2024

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

4. APPLICATION SUBMISSION GUIDELINES

4.1 *Instructions for Applicants* document

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

4.2 Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 8, 2024, and must be submitted by 4 PM central time on June 6, 2024. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3 Submission Deadline Extension

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

including the reason for the extension, will be documented as part of the grant review process records.

4.4 Application Components

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

4.4.1 Abstract and Significance (5,000 characters)

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

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

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

4.4.2 Goals and Objectives (1200 characters each)

List only major **outcome** goals and **measurable** objectives for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within both the stated Objective **and** the Measure sections. Applications may be returned for revision if the proposed metric is not included within the Measure section. Refer to the *Instructions for Applicants* document for details.

The maximum number is 3 outcome goals with 3 objectives each. Projects will be evaluated annually on progress toward **outcome** goals and objectives. See appendix for instructions on writing **outcome** goals and objectives.

A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target (eg, provide 200 clinical services, a 100% increase from a baseline of 100). If a baseline has not yet been defined, applicants are required to explain plans to establish baseline and describe method(s) of measurement.

4.4.3 Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1 and 2 and Months 1, 2, 3, etc, as applicable (eg, Year 1, Months 3-5), NOT specific months or years. Do NOT refer to specific months or years (eg, not December 2024). Month 1 (as opposed to December 1, 2024) is the first full month of the grant award.

4.4.4 Project Plan (12 pages; fewer pages permissible)

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

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

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

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

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

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

4.4.5 References

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

4.4.6 Resubmission Summary

Resubmission applications must include a Resubmission Summary. Use the template provided on the CARS website (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed.

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

4.4.7 CPRIT Grants Summary

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

4.4.8 Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, supplies, contractual expenses, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in section 2.7 will be administratively withdrawn.

- **Personnel:** The individual salary cap for CPRIT awards is $225,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference. Meals are not reimbursable for trips that do not include an overnight stay.
- **Supplies:** Includes medical supplies, medications, office supplies, patient education supplies, computer software/Wi-Fi cards, laptops and iPads, consumable items
- **Other:**
    - **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is $25.
    - Includes Internet services, telephone expenses, printing expenses/copying services, postage, client incentives, service agreements, publication fees.
- **Conference/Seminar Registration Fees (not associated with travel):** Conference and seminar registration fees paid prior to travel should be reported in the "Other" category.
- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Indirect costs reimbursed to subcontractors count toward the total allowable

indirect costs. Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.9 Current and Pending Support and Sources of Funding

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

4.4.10 Biographical Sketches

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

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

Each biographical sketch must not exceed 5 pages and must use the "Prevention Programs: Biographical Sketch" template provided on the CARS (https://CPRITGrants.org) or the NIH Biographical Sketch format. Only biographical sketches will be accepted; do not submit resumes and/or CVs. If a position is not yet filled, please upload a job description.

4.4.11 Personnel and Collaborating Organizations

List ALL paid and unpaid personnel working on the proposed project, including those listed on the Personnel Level of Effort form, as well as partners, collaborators, and anyone listed under the Current & Pending Support section.

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

4.4.12 Letters of Commitment (10 pages)

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

5. APPLICATION REVIEW

5.1 Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process. In the first stage, a peer-review panel will evaluate the applications using the criteria listed below. Peer review panels may be comprised of PRC members, independent reviewers, or a combination thereof. In the second stage, applications judged to be meritorious by the peer review panel will be evaluated by the PRC and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities.

Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The peer review scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

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

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, PRC members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements

regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

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

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

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or a PRC member.

Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2 Review Criteria

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

5.2.1 Primary Evaluation Criteria

Impact

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

Project Strategy and Feasibility

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

Evaluation

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

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners (if applicable) demonstrate the ability to deliver the proposed project?
- Are the appropriate personnel in place or have they been recruited to develop, evaluate, and complete the project?

5.2.2 Secondary Evaluation Criteria

Budget

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

6. AWARD ADMINISTRATION

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

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

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

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

7. CONTACT INFORMATION

7.1 Helpdesk

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

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

7.2 Program Questions

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

Tel: 512-626-2358
Email: prevention@cprit.texas.gov
Website: www.cprit.texas.gov

8. RESOURCES

- The Texas Cancer Registry. https://www.dshs.texas.gov/texas-cancer-registry or contact the Texas Cancer Registry at the Department of State Health Services.
- The Community Guide. https://www.thecommunityguide.org/
- Cancer Control P.L.A.N.E.T. https://cancercontrol.cancer.gov/
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Agency for Healthcare Research and Quality Pathways Community HUB Manual. https://www.ahrq.gov/innovations/hub/index.html
- Dissemination and Implementation Models in Health. https://dissemination-implementation.org/
- Baumann AA, Hooley C, Kryzer E, et al. A scoping review of frameworks in empirical studies and a review of dissemination frameworks. *Implement Sci*. Aug 9 2022;17(1):53. doi:10.1186/s13012-022-01225-4
- Slater MD, Kelly KJ, Thackeray R. Segmentation on a shoestring: health audience segmentation in limited-budget and local social marketing interventions. *Health Promot Pract.* 2006;7(2):170-173.
- Brownson RC, Eyler AA, Harris JK, Moore JB, Tabak RG. Getting the Word Out: New Approaches for Disseminating Public Health Science. *J Public Health Manag Pract.* 2018;24(2):102-111. https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out___New_Approaches_for.4.aspx

9. REFERENCES

1. https://www.cdc.gov/hpv/hcp/answering-questions.html
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services. https://www.cancer-rates.info/tx/

APPENDIX: WRITING GOALS AND OBJECTIVES

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within **both** the stated Objective and the Measure sections (eg, Measure: Number of lesson plans, handout and other materials posted online or delivered in person). The maximum number is 3 goals with 3 objectives each. Projects will be evaluated annually on progress toward **outcome** goals and objectives.

The following has been adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604:

Develop well-defined goals and objectives

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

Goals should be

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

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

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)

  Example: 115 uninsured individuals age 50 and older will complete colorectal cancer screening by March 31, 2019.
- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective

  Example: How many screened at an event? How many completed pre/post assessment?

- Achievable – not only are the objectives themselves possible, but it is also likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved
- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

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

There are 2 types of objectives:

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

There are 3 levels of objectives:

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

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

Summary Table

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

Third-Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Prevention Panel-1_Day 1 (25.1_PRV_PP-1)
Observation Report

Report No.	2024-09-10 25.1_PRV_PP-1
Program Name:	Prevention
Panel Name:	25.1 Prevention Panel-1_Day 1 (25.1 _PRV_PP-1)
Panel Date:	September 10, 2024
Report Date:	September 16, 2024

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 25.1 Prevention Panel-1_Day 1 (25.1_PRV_PP-1) meeting. The meeting was chaired by Nancy Lee and conducted via videoconference on September 10, 2024.

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) application were discussed and eight (8) applications were not discussed
- Panelists: One (1) panel chair, twelve (12) reviewers, and three (3) advocate reviewers
- Oversight Committee Members: One (1)
- 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 four (4) Conflicts of Interest (COI) 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.

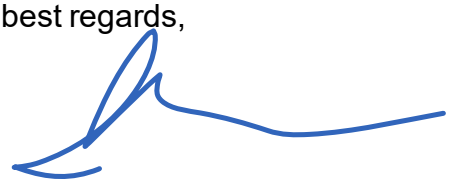
CONCLUSION

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, CRMA, 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) 25.1 Prevention Peer Review Day 2 (25.1_PRV_PP-1_Day 2) Observation Report

Report No.	2024-09-11 25.1_PRV_PP-1 Day 2
Program Name:	Prevention
Panel Name:	25.1 Prevention Peer Review Day 2 (25.1 _PRV_PP-1 Day 2)
Panel Date:	September 11, 2024
Report Date:	September 16, 2024

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 25.1 Prevention Peer Review Day 2 (25.1_PRV_PP-1 Day 2) meeting. The meeting was chaired by Nancy Lee and conducted via videoconference on September 11, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and eighteen (18) applications were not discussed
- Panelists: One (1) panel chair, eleven (11) expert reviewers, and three (3) 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: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) Conflicts of Interest (COI) 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.

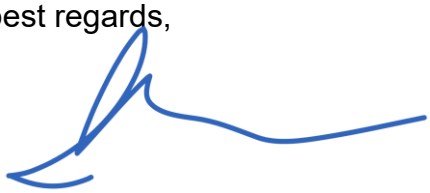
CONCLUSION

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, CRMA, 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)
25.1 Prevention Review Council Programmatic Review
(25.1_PRV_PRC)
Observation Report

Report No.	2024-10-18 25.1_PRV_PRC
Program Name:	Prevention
Panel Name:	25.1 Prevention Review Council Programmatic Review (25.1_PRV_PRC)
Panel Date:	October 18, 2024
Report Date:	October 22, 2024

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 25.1 Prevention Review Council Programmatic Review (25.1_PRV_PRC) meeting. The meeting was chaired by Stephen Wyatt and conducted via videoconference on October 18, 2024.

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 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 eight (8) applications were not discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were 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, CRMA, 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 Prevention Cycle 25.1

Awards Announced at the November 20, 2024, Oversight Committee Meeting

The following table lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention cycle 25.1 include those received in response to the following Requests for Applications: *Cancer Screening and Early Detection; Dissemination of CPRIT-Funded Cancer Control Interventions;* and *Primary Prevention of Cancer*.

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:			
PP250004	Minnix, Jennifer	The University of Texas M.D. Anderson Cancer Center	Mahoney, Martin
Applications not considered by the PIC or Oversight Committee:			
PP250017	Strong, Larkin	The University of Texas M.D. Anderson Cancer Center	Thomson, Cynthia
PP250041	Lapiz-Bluhm, Maria Danet	The University of Texas Health Science Center at San Antonio	Moreno, Patricia
PP250045	Chen, Lei-Shih	Texas A&M University System Health Science Center	Tseng, Tung-Sung

De-Identified Overall Evaluation Scores

Dissemination of CPRIT-Funded Cancer Control Interventions

Prevention Cycle 25.1

Application ID	Final Overall Evaluation Score
PP250018*	3.8

* Recommended for funding.

Final Overall Evaluation Scores and Rank Order Scores

Dr. David Cummings
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dcummingsmd@yahoo.com

Kristen Doyle
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to kdoyle@cprit.texas.gov

Dear Dr. Cummings and Ms. Doyle,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for the FY2025 Cycle 1 Cancer Screening and Early Detection (CSD), Primary Prevention of Cancer (PPC), and Dissemination of CPRIT-Funded Cancer Control Interventions (DI) grant awards.

The PRC met on October 18, 2024, to consider the applications recommended by the peer review panel following their September 10 -11, 2024, meeting. The PRC recommends 8 projects totaling $13,446,501.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The average score for recommended applications ranges from 2.7 to 4.2, with an average score of 3.54. The PRC made no changes to the goals, project objectives, or timelines of the applications.

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

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

Attachment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cycle 25.1 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP250006	CSD	Expansion of Cancer Screening and Early Detection Services to Rural & Medically Underserved Communities	Duckworth, Jessica	The Rose	2.7	1	$2,500,000
PP250019	CSD	Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas	Argenbright, Keith	The University of Texas Southwestern Medical Center	3.1	2	$1,499,243
PP250016	PPC	Screening and treatment for unhealthy alcohol use for cancer prevention in Central Texas – 2	Calderon-Mora, Jessica	The University of Texas at Austin	3.4	3	$1,000,000
PP250046	CSD	The Houston Prevenir, Ayudar, Poder (PAP) Project	Zamorano, Abigail	The University of Texas Health Science Center at Houston	3.6	4	$1,499,997
PP250004	CSD	A Virtual, Centralized Lung Cancer Screening Program for Northeast Texas	Minnix, Jennifer	The University of Texas M. D. Anderson Cancer Center	3.7	5	$1,497,342
PP250009	CSD	The Central Texas Colorectal Cancer Screening Program (CTX-CCSP)	Shokar, Navkiran	The University of Texas at Austin	3.8	6	$2,500,000
PP250018	DI	Texas Comprehensive Access & Resources for Early Lung Cancer Prevention (TEX-CARE)	Zoorob, Roger	Baylor College of Medicine	3.8	7	$449,929
PP250005	CSD	Project 80% Colorectal Cancer Screening Program	Foxhall, Lewis	The University of Texas M. D. Anderson Cancer Center	4.2	8	$2,499,990

CSD: Cancer Screening and Early Detection
PPC: Primary Prevention of Cancer
DI: Dissemination of CPRIT-Funded Cancer Control Interventions

Cancer Prevention & Research
Institute of Texas

CEO Affidavit
Supporting Information

Prevention
FY 2025—Cycle 1
Primary Prevention of Cancer

Request for Applications

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA P-25.1-PPC

Primary Prevention of Cancer

Please also refer to the Instructions for Applicants document

Application Receipt Opening Date: March 7, 2024

Application Receipt Closing Date: June 6, 2024

FY 2025

Fiscal Year Award Period

September 1, 2024-August 31, 2025

TABLE OF CONTENTS

RFA VERSION HISTORY

Rev 2/9/2024 RFA release

Rev 3.7.2024 Section 4.4.2 – Goals and Objectives

- Goals and Objectives character limits were increased to 1200 characters each

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

1.1 Prevention Program Priorities

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

Established Principles:

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

CPRIT's Cross-Program Priorities:

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

Prevention Program Priorities:

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services
- Assess the CPRIT Prevention Program to identify best practices, use as a quality improvement tool, and guide future program direction.

2. FUNDING OPPORTUNITY DESCRIPTION

2.1 Summary

The ultimate goals of the CPRIT Prevention Program are to reduce cancer incidence and mortality, reduce cancer disparities, and improve the lives of cancer survivors. More than half of cancers can be prevented by applying prevention knowledge we already have about modifiable causes of cancer. We can prevent some cancers, including second primary cancers in cancer survivors, by promoting and providing hepatitis B and HPV vaccines, supporting environmental approaches that make healthy choices easier, and empowering people to make healthy lifestyle choices related to tobacco use, nutrition, physical activity, and sun safety. This failure to address prevention is particularly impactful for those experiencing cancer disparities (eg, minority population groups, low-income populations). When prevention programs are comprehensive and maximize the ability for all populations to participate, major changes in behaviors and morbidity and mortality can be achieved. (Colditz GA, Emmons KM. Accelerating the Pace of Cancer Prevention-Right Now. *Cancer Prev Res [Phila].* 2018;11[4]:171-184)

There is increasing focus on multilevel interventions for cancer prevention. (Clauser SB, Taplin SH, Foster MK, Fagan P, Kaluzny AD. Multilevel Intervention Research: Lessons Learned and Pathways Forward. *J Natl Cancer Inst Monogr.* 2012;44:127-133) A multilevel intervention seeks to influence more than 1 contextual level, ie, individual, group, organization, and community. Multilevel interventions require action targeting 2 or more levels of influence at the same time or in close temporal proximity. Multilevel interventions may involve policy, systems, and

environmental change as a way of modifying the environment to make healthy choices practical and available to all community members.

The **Primary Prevention of Cancer (PPC)** award mechanism focuses on increasing implementation of evidence-based strategies to ensure that all Texans benefit from the cancer prevention knowledge that we currently have. CPRIT seeks to fund multilevel interventions to reduce cancer risk, disease burden, and cancer disparities for priority populations, including cancer survivors. Modifiable risk behaviors include tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, sun exposure, HPV vaccination, hepatitis B vaccination, and environmental/occupational cancer exposures. **NOTE: The PPC award mechanism will not support cancer prevention/intervention research**; projects must be focused on implementing existing, evidence-based prevention approaches. Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).

This award mechanism also focuses on improving health outcomes among cancer survivors. Evidence suggests that lifestyle factors such as cessation of tobacco use, weight control, dietary choices, and physical activity substantially influence overall health and survival after a cancer diagnosis. These modifiable behaviors are risk factors for second primary cancers and comorbidity among cancer survivors. Decreasing alcohol intake is associated with cardioprotective effects, which may provide some benefits among survivors who have an increased risk of cardiovascular disease.

Applications should also assess and address social determinants that contribute to cancer burden and disparities (eg, cultural factors, unmet needs, access barriers). Interventions and communications should be structured to address the unique circumstances of the population to be served.

Eligible applications must include the delivery of interventions to nonmetropolitan (rural) and/or medically underserved counties in the state. For example, cigarette smoking and smokeless tobacco use are more prevalent in rural populations. Higher rates of obesity, lower rates of physical activity, and poor diets contribute to cancer-related health disparities in rural populations and high-risk urban populations.

Partnerships with other organizations that can support and leverage resources are strongly encouraged. A coordinated submission of a collaborative partnership program in which all partners have a substantial role in the proposed project is preferred.

2.2 Project Objectives

CPRIT seeks to reduce modifiable risk behaviors via projects that will do 1 or more of the following:

- Establish collaborations and partnerships with communities to deliver multilevel, evidence-based projects to reduce disparities and achieve health equity
- Deliver multilevel, evidence-based projects that include public and/or professional education, outreach, navigation to and delivery of primary prevention interventions
- Implement policy, systems and environmental changes that are sustainable over time (See https://www.cccnationalpartners.org/new-resource-policy-systems-and-environmental-change-resource-guide); examples include the following:
    - Advocating for/supporting structures that provide shade, sidewalks, paths, and recreation areas in community design
    - Implementing Farm to School programs (See https://farmtoschoolcensus.fns.usda.gov/)
    - Increasing availability of healthy food choices in restaurants or cafeterias
    - Advocating for/supporting policies for smoke-free zones and public events
    - Implementing programs that result in sustained smoking cessation.

2.3 Award Description

The **Primary Prevention of Cancer** RFA solicits applications for eligible projects up to 3 years in duration that will deliver multilevel, evidence-based interventions that improve cancer-related health behaviors, including improving the quality of life and cancer outcomes for cancer survivors. Interventions may address tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, HPV vaccination, hepatitis B vaccination, and environmental/occupational cancer exposures. Nonmetropolitan (rural) and/or medically underserved populations must be included in the defined service area.

The following are required components of the project:

- **Evidence-Based:** CPRIT's primary prevention grants are intended to fund culturally appropriate, effective, and efficient systems of delivery of preventive services based on the existing body of knowledge about and evidence for cancer prevention. Evidence-based and promising interventions can be identified via the Community Guide, What Works for Health, National Comprehensive Cancer Control Program, NCI Evidence-Based Cancer Control Programs, and other sources.

  The National Comprehensive Cancer Network and the American Cancer Society have developed consensus-based comprehensive survivorship care guidelines to provide direction on managing the potential physical and psychosocial long-term impact of cancer/associated treatment and subsequent surveillance for recurrence and screening for second primary cancers for projects focusing on survivor care.

  If evidence-based interventions have not been implemented or evaluated for the specific population or setting proposed, provide evidence that the proposed intervention is appropriate for the population and has a high likelihood of success (ie, an evidence-informed practice). In cases where the evidence base is still developing, the applicant should provide a strong and comprehensive evaluation plan allowing for documentation of new evidence over the life of the project.
- **Multilevel Interventions:** Health behaviors have multiple levels of influences, often including individual, group, organization, and community determinants. Influences on behaviors interact across these different levels, and multilevel interventions are the most effective in changing behavior (See http://medbox.iiab.me/modules/en-cdc/www.cdc.gov/cancer/crccp/sem.htm).
- **Geographic Area to be Served:** Preventive service delivery to nonmetropolitan/medically underserved area (MUA) counties must be included in the defined service area. Rural and MUA counties may be identified via web-based tools from the Texas Department of State Health Services and US Department of Health and Human Services. Service to urban counties that are not medically underserved is allowable as long as the project proposes to also serve nonmetropolitan counties that are medically underserved.

- **Community Partner Networks:** Applicants are strongly encouraged to coordinate and describe a collaboration of community partners that can deliver services to the most counties and the most people possible in a selected service region. Partnerships with other organizations that can support and leverage resources (eg, community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations) are encouraged. Letters of commitment or memoranda of understanding describing their specific role in the partnership will strengthen the application.

CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based interventions to modify cancer risk factors, changes in provider practice, and systems changes. Applicants must demonstrate how these outcomes will ultimately impact incidence, mortality, morbidity, disparities, or quality of life. Under this RFA, CPRIT **will not** consider the following:

- Projects focused solely on metropolitan/non-medically underserved counties.
- Projects focusing solely on systems and/or policy change or solely on education and/or outreach that do not include the navigation to and delivery of multilevel interventions to reduce cancer risk.
- Projects focusing solely on case management/patient navigation services. Case management/patient navigation services must be paired with the delivery of a cancer prevention service, including those practices delivered by another provider.
- Cancer preventive services proposed as part of the project that do not comply with established and current national guidelines.
- Projects involving prevention/intervention research. Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).

2.4 Priorities

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

(1) Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.

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

- Underinsured and uninsured individuals
- Medically under resourced communities
- Historically underserved or underrepresented racial, ethnic, and cultural minority groups

(2) Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.

While disparities and needs exist across the state, CPRIT will also prioritize applications proposing to serve geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence. While it is permissible to serve metropolitan areas, projects must propose to also serve nonmetropolitan and/or MUAs of the state.

Geographic and Population Balance in Current CPRIT Portfolio

At the programmatic level of review conducted by the PRC (section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention Program portfolio (see https://www.cprit.texas.gov/our-programs/prevention/portfolio-maps and https://www.cprit.texas.gov/grants-funded?search=prevention).

2.5 Outcome Metrics

Applicants are required to clearly describe their assessment and evaluation methodology. Mixed-methods evaluations are encouraged (eg, qualitative, quality improvement methods). The applicant is required to describe final outcome measures for the project. These measures should be identified in the project plan (including a logic model) and will serve as a measure of program effectiveness. Planned policy, system, or environmental changes should be identified. In addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to conduct a meaningful evaluation.

Reporting Requirements

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

If someone other than the PD will enter information in the progress reports, they must be named as an Alternate Submitter in CARS. The Alternate Submitter is an application contact designated by the PD to complete PD tasks in CARS and/or the grants management system.

If services are being paid for and provided by others, the applicant is required to report on the number and outcomes of these preventive services.

2.6 Funding Information

The amount of total funding that applicants may request is dependent on the primary focus of the project and on the type of project: New, Initial Expansion, or Maintenance Expansion (see Expansion Policy, section 2.9). Use the table below to determine the maximum amount of funding and the maximum number of years that may be requested.

Project Type	Maximum Amount of Total Funding	Maximum Duration
New Project	$1 million	3 years
Initial Expansion	$1 million	3 years
Initial Expansion – Vaccination or Tobacco Cessation for Adults	$1.5 million	3 years
Maintenance Expansion	$2 million	5 years
Maintenance Expansion – Vaccination or Tobacco Cessation for Adults	$2.5 million	5 years

The funding amount is inclusive of both direct and indirect costs. Grant funds may be used to pay for preventive services, navigation services, project staff salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s).

Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

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

2.7 Eligibility

- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field and who resides in Texas during the time that the project is conducted.
- The applicant may submit more than 1 application, but each application must be for distinctly different services without overlap in the services provided. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review.
- If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary. Duplicative applications will be administratively withdrawn.
- 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 applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.

- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.
- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 6. All statutory provisions and relevant administrative rules can be found on the CPRIT website.

2.8 Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. Resubmission applications must include a Resubmission Summary (see section 4.4.10).
- Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

2.9 Expansion Policy

- Expansion grants are intended to fund expansion of currently or previously funded projects that have demonstrated exemplary success, as evidenced by progress reports and project evaluations, and desire to further enhance their impact on priority populations. Detailed descriptions of **results, barriers, outcomes, and impact of the currently or previously funded project are required** (see outline of Most Recently Funded Project Summary, section 4.4.11).
- Proposed expansion projects should NOT be new projects but should closely follow the intent and core elements of the currently or previously funded project. Established infrastructure/processes are required.
- Expansion of current projects into geographic areas not well served by the CPRIT Prevention portfolio (see maps at http:// www.cprit.state.tx.us/our-programs/prevention/portfolio-maps) will receive priority consideration.
- Fully described prior results of the project upon which the initial or maintenance expansion is based should be provided. These include but are not limited to services delivered, measured outcomes, policy/system/environmental changes implemented, and program evaluation results.
- CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area). It is expected that baselines will have already been established and that continued improvement over baseline is demonstrated in the current application. However, in the case of a proposed expansion where no baseline data exist for the priority population, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline. Applicants must demonstrate how these outcomes will ultimately impact cancer incidence, mortality, morbidity, or quality of life.
- CPRIT also expects that applications for continuation **will not** require startup time, that applicants can demonstrate that they have overcome barriers encountered, and that applicants have identified **lasting systems changes** that improve results, efficiency, and sustainability. Leveraging of resources and plans for dissemination are expected and should be well described.

Requirements for Initial and Maintenance Expansion Projects

Initial Expansion: For the first expansion application, eligible applicants should propose to expand their programs to include additional types of primary preventive practices or to expand current practices into additional counties. In either case, the expansion must include the delivery of services to nonmetropolitan (rural) and/or medically underserved counties in the state. These may be identified via web-based tools from the Texas Department of State Health Services and US Department of Health and Human Services.

Maintenance Expansion: For a subsequent expansion, additional primary preventive practices and/or expansion to additional counties are optional; however, the counties and the practices offered in the first expansion should not be decreased. The number of services delivered during the maintenance expansion must be increased substantially if no further geographic or preventive service expansion is proposed.

3. KEY DATES

RFA release	February 9, 2024
Online application opens	March 7, 2024, 7 AM central time
Application due	June 6, 2024, 4 PM central time
Application review	June-September 2024
Award notification	November 2024
Anticipated start date	December 1, 2024

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

4. APPLICATION SUBMISSION GUIDELINES

4.1 Instructions for Applicants document

It is **imperative** that applicants read the accompanying instructions document for this RFA (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2 Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered**

eligible for evaluation. The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 7, 2024, and must be submitted by 4 PM central time on June 6, 2024. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3 Submission Deadline Extension

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

4.4 Application Components

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

4.4.1 Abstract and Significance (5,000 characters)

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

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

- **Need:** Include a description of need in the specific service area. Include rates of incidence, mortality, and screening in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the priority population to be served.

- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of preventive services to be delivered and number of people (public and/or professionals) to be served.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.4.2 Goals and Objectives (1200 characters each)

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within both the stated Objective **and** the Measure sections (eg, Measure: 2,000 individuals, ages 9-12, will initiate HPV vaccination during the grant period). Refer to the *Instructions for Applicants* document for details.

The maximum number is 3 goals with 3 outcome objectives each. Projects will be evaluated annually on progress toward outcome goals and objectives. See appendix B for instructions on writing outcome goals and objectives.

A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target (eg, provide 200 clinical services, a 100% increase from a baseline of 100). If a baseline has not been defined,applicants are required to explain plans to establish baseline and describe method(s) of measurement. Note that character limits are inclusive of all words in each text box, including provided headings.

4.4.3 Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3, and Months 1, 2, 3, etc, as applicable (eg, Year 1, Months 3-5). Do NOT refer to specific months or years (eg, not May 2024). Month 1 (as opposed to March 1, 2024) is the first full month of the grant award.

4.4.4 Project Plan (12 pages; fewer pages permissible)

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

Background: Briefly present the rationale behind the proposed primary prevention services, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to beimplemented for the priority population. Describe the race, ethnicity, age, and other defining characteristics of the population to be served.

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the priority population and proposed service area are required where applicable.

Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are encouraged.

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

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services, as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Describe why this project is nonduplicative. If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary.

It is important to distinguish between Texas counties where the project proposes to deliver services and counties of residence of population served (see appendix A for definitions and *Instructions for Applicants*). Only counties where service delivery occurs should be listed in the Geographic Area to be Served section of the application. Projecting counties of residence of population served is not required but may be described in the project plan.

Clearly demonstrate the ability to provide the proposed service(s) and describe how results will be

improved over baseline and the ability to reach the priority population.

If preventive services are being paid for and provided by others, the applicant must explain and report on the number of these services and outcomes.

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

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing health programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. The applicant should demonstrate how the organizational environment will contribute to a successful project. If equipment or physical resources are required to carry out the project, the applicant should describe the availability of these resources and the organizational capacity to use equipment. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

Project Maintenance and Sustainability: CPRIT acknowledges that full maintenance and sustainability of projects when CPRIT funding ends may not be feasible, especially in cases involving the delivery of preventive services. However, it is important to consider sustainability early in the life cycle of a project, particularly regarding organizational characteristics and processes that are modifiable.

Washington University in St Louis has developed a useful tool (Program Sustainability Assessment Tool) to assess program capacity for sustainability. The tool assesses several factors that contribute to program sustainability. These factors include environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communication,

and strategic planning. Applicants are not required to use this tool; however, it provides practical guidance on factors that should be considered and should be included in the application to describe a program's organizational capacity for sustainability.

It is expected that steps toward building capacity for the program will be taken and plans for such should be described in the application. The applicant should describe the factors that will contribute to the organization's capacity to facilitate sustainability.

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

While passive dissemination methods are common (eg, publications, presentations at professional meetings), plans should include some active dissemination methods (eg, meetings with stakeholders, blogs, social media). Applicants should describe their dissemination plans. The plans should include the kinds of audiences to be targeted and methods for reaching the targeted audiences.

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

4.4.5 People Reached (Indirect Contact)

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

4.4.6 Number of Unique People Served (Direct Contact)

Provide the estimated overall number of unique members of the public and professionals served by

the funded project. One person may receive multiple services but should only be counted once here. Refer to appendix A for definitions.

4.4.7 Number of Services Delivered (Direct Contact)

Provide the estimated overall number of services directly delivered to members of the public and to professionals by the funded project. Each individual service should be counted, regardless of the number of services 1 person receives. The applicant is required to itemize separately the education, navigation, and cancer prevention activities/services, with estimates, that led to the calculation of the overall estimate provided. Refer to appendix A for definitions.

4.4.8 Number of Preventive Services Delivered

Provide the estimated overall number of services directly delivered to members of the public by the funded project. Each individual clinical service should be counted, regardless of the number of services 1 person receives. Separately itemize the services, with estimates, that led to the calculation of the overall estimate provided. Refer to appendix A for definitions.

4.4.9 References

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

4.4.10 Resubmission Summary

Resubmission applications must include a Resubmission Summary. Use the template provided on the CARS website (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed.

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

4.4.11 Most Recently Funded Relevant CPRIT Prevention Project Summary (only if applicable) (3 pages)

Upload a summary that outlines the progress made with the applicant's most recently funded relevant CPRIT Prevention Award. Applicants must describe results and outcomes of the most recently funded award and demonstrate why further funding is warranted.

Please note that a different set of reviewers from those assigned to the previously funded application may evaluate this application. Applicants should make it easy for reviewers to compare the most recently funded project with the proposed project.

In the description, include the following:

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

4.4.12 CPRIT Grants Summary

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

4.4.13 Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services

delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis.

Applications requesting more than the maximum allowed cost as specified in section 2.6 will be administratively withdrawn.

Clearly describe any organizational cost sharing or pro bono contributions related to this project, as well as any attempts made or successes to secure other state/federal funds.

- **Average Cost per Person:** The average cost per person will be automatically calculated from the total cost of the project divided by the total number of unique people served (refer to appendix A).
- **Average Cost per Service:** The average cost per service will be automatically calculated from the total cost of the project divided by the total number of services delivered (refer to appendix A). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Average Cost per Preventive Service:** The average cost per clinical service will be automatically calculated from the total cost of the project divided by the total number of services delivered (refer to appendix A).
- **Personnel:** The individual salary cap for CPRIT awards is $225,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference. Meals are not reimbursable for trips that do not include an overnight stay.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Cost sharing of equipment purchases is strongly encouraged**.**
- **Services Costs:** CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested. If preventive services are being paid for and provided by others, the applicant is required to explain and report on the number of services and outcomes that are delivered to the people navigated by the program.

- **Supplies:** Includes medical supplies, medications, office supplies, patient education supplies, computer software/Wi-Fi cards; laptops and iPads, consumable items.
- **Other:**
  - **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is $25.
  - Includes Internet services, telephone expenses, printing expenses/copying services, postage, client incentives, service agreements, publication fees.
  - **Conference/Seminar Registration Fees (not associated with travel):** Conference and seminar registration fees paid prior to travel should be reported in the "Other" category.
- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Indirect costs reimbursed to subcontractors count toward the total allowable indirect costs. Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.14 Current and Pending Support and Sources of Funding

Use the template provided on the CARS (https://CPRITGrants.org). Describe the funding source and duration of **all** current and pending support for the proposed project.

4.4.15 Biographical Sketches

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

- Use the Co-PD Biographical Sketch section ONLY if a Co-PD has been identified.
- The evaluation professional must provide a biographical sketch in the Evaluation Professional Biographical Sketch section.

- Up to 3 additional biographical sketches for key personnel may be provided in the Key Personnel Biographical Sketches section.

Each biographical sketch must not exceed 5 pages and should use either the "Prevention Programs: Biographical Sketch" template provided on the CARS (https://CPRITGrants.org) or the NIH Biographical Sketch format. If a position is not yet filled, please upload a job description.

4.4.16 Personnel and Collaborating Organizations

List ALL paid and unpaid personnel working on the proposed project, including those listed on the Personnel Level of Effort form, as well as partners, collaborators, and anyone listed under the Current & Pending Support section.

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

4.4.17 Letters of Commitment (10 pages)

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

5. APPLICATION REVIEW

5.1 Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the PRC. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the PRC and recommended for funding based oncomparisons with applications from all of the review panels and programmatic priorities.

Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The peer review scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be

given to proposed projects that target geographic regions of the state or population subgroups that are notwell represented in the current CPRIT Prevention project portfolio.

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

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

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

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website.

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

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or PRC 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.

5.2 Review Criteria

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

5.2.1 Primary Evaluation Criteria

Impact

- Do the proposed approaches address an important problem or need in primary prevention of cancer? Do the proposed project strategies support desired outcomes in cancer risk and equity? Do the proposed project strategies reach a priority population (eg, low income, minority, rural) at high risk of cancer?
- Will the project serve and impact an appropriate number of people based on the budget allocated?
- If applicable, have partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than the applicant organization's effort separately?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the priority population? Is the base of evidence clearly explained and referenced?

Project Strategy and Feasibility

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

- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described?
- Does the program leverage partners and resources to maximize the reach of the practices proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

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

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive practices?
- Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to design, implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?
- Does the applicant describe the program's organizational capacity for sustainability?

- Does the applicant describe steps that will be taken toward building internal capacity and partnerships?
- Does the applicant describe a plan for systems changes that are sustainable over time (eg, improve results, provider practice, efficiency, cost-effectiveness)?

5.2.2 Secondary Evaluation Criteria

Budget

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

Dissemination and Replication

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

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in 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. 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 quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year. In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1 Helpdesk

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

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

7.2 Program Questions

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

Tel:	512-626-2358
Email:	prevention@cprit.texas.gov
Website:	www.cprit.texas.gov

8. RESOURCES

- Department of State Health Services. https://www.dshs.texas.gov/tcr/data/modifiable-risk-factors.aspx
- The Community Guide. https://www.thecommunityguide.org/
- Implementing Farm to School Programs. https://farmtoschoolcensus.fns.usda.gov/
- What Works for Health. https://www.countyhealthrankings.org/take-action-to-improve-health/what-works-for-health
- National Comprehensive Cancer Control Program. https://www.cdc.gov/cancer/ncccp/index.htm
- NCI Evidence-Based Cancer Control Program. https://ebccp.cancercontrol.cancer.gov/index.do
- Evidence-Based Cancer Control Programs (EBCCP). https://ebccp.cancercontrol.cancer.gov/
- Comprehensive Cancer Control. Policy, Systems, and Environmental Change Resource Guide. https://www.cccnationalpartners.org/new-resource-policy-systems-and-environmental-change-resource-guide
- Colorectal Cancer Control Program. Social Ecological Model. http://medbox.iiab.me/modules/en-cdc/www.cdc.gov/cancer/crccp/sem.htm
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Program Sustainability Assessment Tool, copyright 2012, Washington University, St Louis, MO, https://www.sustaintool.org/about-us/
- Getting the Word Out: New Approaches for Disseminating Public Health Science. Ross C. Brownson, RC; Eyler, AA; Harris, JK; Moore, JB; Tabak, RG. *Journal of Public Health Management & Practice.* 2018;24(2):102-111. https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out__New_Approaches_for.4.aspx

- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs. http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Environmental and Occupational Interventions for Primary Prevention of Cancer: A Cross-Sectorial Policy Framework. https://ehp.niehs.nih.gov/doi/10.1289/ehp.1205897?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. https://www.cdc.gov/os/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

9. REFERENCES

1. https://www.cdc.gov/hpv/hcp/answering-questions.html
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services. https://www.cancer-rates.info/tx/
3. Colditz GA, Emmons KM. Accelerating the Pace of Cancer Prevention- Right Now. *Cancer Prev Res (Phila).* 2018;11(4):171-184
4. Clauser SB, Taplin SH, Foster MK, Fagan P, Kaluzny AD. Multilevel intervention research: lessons learned and pathways forward. *J Natl Cancer Inst Monogr.* 2012;(44):127-133

APPENDIX A: KEY TERMS

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

- **Evidence-Based Program:** A program that is validated by some form of documented research or applied evidence.
- **Goals:** Broad statements of general purpose to guide planning. Outcome goals should be few in number and focus on aspects of highest importance to the project (appendix B).
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- **Navigation Services:** Number of activities/services that offer assistance to help overcome health care system barriers in a timely and informative manner to improve health care access and outcomes. Examples include patient reminders, transportation assistance, and appointment scheduling assistance. One individual may receive multiple navigation services.
- **Number of Preventive Services/Practices:** Number of preventive services delivered directly to members of the public by the funded project. Number of evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Examples include, but are not limited to vaccinations, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments and services. One individual may receive multiple preventive services.
- **Number of Services (Direct Contact):** Number of services delivered directly to members of the public and/or professionals—direct, interactive public or professional education, outreach, training, navigation service, or clinical service, such as live educational and/or training sessions, vaccine administration, case management/navigation services, and physician consults. One individual may receive multiple services.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outcomes; example: "Increase screening service provision in X population from Y% to Z% by the end of Year 1." Baseline data for the priority population must be included as part of each objective (appendix B). The proposed metric should be included in **both** the objective andthe measure.
- **People Reached (Indirect Contact):** Number of members of the public and/or professionals reached via indirect noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public

service announcements, newsletters, and journals. (This category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals whowould be reached through activities that occur as a direct consequence of the CPRIT- funded project's leveraging of other resources/funding to implement the CPRIT-funded project).

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

APPENDIX B: WRITING GOALS AND OBJECTIVES

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within **both** the stated Objective and the Measure sections (eg, Measure: 2,000 individuals, ages 9-12, will initiate HPV vaccination during the grant period).

The maximum number is 3 goals with 3 objectives each. Projects will be evaluated annually on progress toward **outcome** goals and objectives.

The following has been adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604:

Develop well-defined goals and objectives.

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

Goals should be

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

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

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)
    - Example: 115 uninsured individuals aged 50 and older will complete colorectal cancer screening by March 31, 2018.
- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective

- Example: How many screened at an event? How many completed pre/post assessment?
- Achievable – not only are the objectives themselves possible, but it is also likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved
- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

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

There are 2 types of objectives:

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

There are 3 levels of objectives:

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

- Behaviors (past or current) – to act in a particular way (will exercise 30+ minutes a day, will have a mammogram)

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

Summary Table

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

Third-Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Prevention Panel-1_Day 1 (25.1_PRV_PP-1)
Observation Report

Report No.	2024-09-10 25.1_PRV_PP-1
Program Name:	Prevention
Panel Name:	25.1 Prevention Panel-1_Day 1 (25.1 _PRV_PP-1)
Panel Date:	September 10, 2024
Report Date:	September 16, 2024

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 25.1 Prevention Panel-1_Day 1 (25.1_PRV_PP-1) meeting. The meeting was chaired by Nancy Lee and conducted via videoconference on September 10, 2024.

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) application were discussed and eight (8) applications were not discussed
- Panelists: One (1) panel chair, twelve (12) reviewers, and three (3) advocate reviewers
- Oversight Committee Members: One (1)
- 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 four (4) Conflicts of Interest (COI) 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.

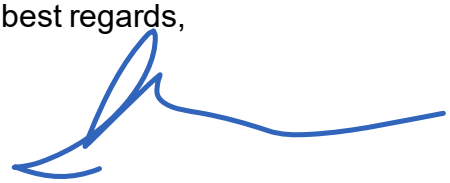
CONCLUSION

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, CRMA, 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) 25.1 Prevention Peer Review Day 2 (25.1_PRV_PP-1_Day 2) Observation Report

Report No.	2024-09-11 25.1_PRV_PP-1 Day 2
Program Name:	Prevention
Panel Name:	25.1 Prevention Peer Review Day 2 (25.1 _PRV_PP-1 Day 2)
Panel Date:	September 11, 2024
Report Date:	September 16, 2024

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 25.1 Prevention Peer Review Day 2 (25.1_PRV_PP-1 Day 2) meeting. The meeting was chaired by Nancy Lee and conducted via videoconference on September 11, 2024.

PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and eighteen (18) applications were not discussed
- Panelists: One (1) panel chair, eleven (11) expert reviewers, and three (3) 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: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were four (4) Conflicts of Interest (COI) 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.

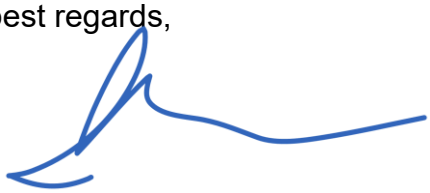
CONCLUSION

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, CRMA, 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)
25.1 Prevention Review Council Programmatic Review
(25.1_PRV_PRC)
Observation Report

Report No.	2024-10-18 25.1_PRV_PRC
Program Name:	Prevention
Panel Name:	25.1 Prevention Review Council Programmatic Review (25.1_PRV_PRC)
Panel Date:	October 18, 2024
Report Date:	October 22, 2024

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 25.1 Prevention Review Council Programmatic Review (25.1_PRV_PRC) meeting. The meeting was chaired by Stephen Wyatt and conducted via videoconference on October 18, 2024.

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 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 eight (8) applications were not discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were 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, CRMA, 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 Prevention Cycle 25.1

Awards Announced at the November 20, 2024, Oversight Committee Meeting

The following table lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention cycle 25.1 include those received in response to the following Requests for Applications: *Cancer Screening and Early Detection; Dissemination of CPRIT-Funded Cancer Control Interventions;* and *Primary Prevention of Cancer*.

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:			
PP250004	Minnix, Jennifer	The University of Texas M.D. Anderson Cancer Center	Mahoney, Martin
Applications not considered by the PIC or Oversight Committee:			
PP250017	Strong, Larkin	The University of Texas M.D. Anderson Cancer Center	Thomson, Cynthia
PP250041	Lapiz-Bluhm, Maria Danet	The University of Texas Health Science Center at San Antonio	Moreno, Patricia
PP250045	Chen, Lei-Shih	Texas A&M University System Health Science Center	Tseng, Tung-Sung

De-Identified Overall Evaluation Scores

Primary Prevention of Cancer

Prevention Cycle 25.1

Application ID	Final Overall Evaluation Score
PP250016*	3.4
H	4.4
I	4.8
J	5.3
K	5.3

* Recommended for funding.

Final Overall Evaluation Scores and Rank Order Scores

Dr. David Cummings
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dcummingsmd@yahoo.com

Kristen Doyle
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to kdoyle@cprit.texas.gov

Dear Dr. Cummings and Ms. Doyle,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for the FY2025 Cycle 1 Cancer Screening and Early Detection (CSD), Primary Prevention of Cancer (PPC), and Dissemination of CPRIT-Funded Cancer Control Interventions (DI) grant awards.

The PRC met on October 18, 2024, to consider the applications recommended by the peer review panel following their September 10 -11, 2024, meeting. The PRC recommends 8 projects totaling $13,446,501.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The average score for recommended applications ranges from 2.7 to 4.2, with an average score of 3.54. The PRC made no changes to the goals, project objectives, or timelines of the applications.

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

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

Attachment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cycle 25.1 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP250006	CSD	Expansion of Cancer Screening and Early Detection Services to Rural & Medically Underserved Communities	Duckworth, Jessica	The Rose	2.7	1	$2,500,000
PP250019	CSD	Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas	Argenbright, Keith	The University of Texas Southwestern Medical Center	3.1	2	$1,499,243
PP250016	PPC	Screening and treatment for unhealthy alcohol use for cancer prevention in Central Texas – 2	Calderon-Mora, Jessica	The University of Texas at Austin	3.4	3	$1,000,000
PP250046	CSD	The Houston Prevenir, Ayudar, Poder (PAP) Project	Zamorano, Abigail	The University of Texas Health Science Center at Houston	3.6	4	$1,499,997
PP250004	CSD	A Virtual, Centralized Lung Cancer Screening Program for Northeast Texas	Minnix, Jennifer	The University of Texas M. D. Anderson Cancer Center	3.7	5	$1,497,342
PP250009	CSD	The Central Texas Colorectal Cancer Screening Program (CTX-CCSP)	Shokar, Navkiran	The University of Texas at Austin	3.8	6	$2,500,000
PP250018	DI	Texas Comprehensive Access & Resources for Early Lung Cancer Prevention (TEX-CARE)	Zoorob, Roger	Baylor College of Medicine	3.8	7	$449,929
PP250005	CSD	Project 80% Colorectal Cancer Screening Program	Foxhall, Lewis	The University of Texas M. D. Anderson Cancer Center	4.2	8	$2,499,990

CSD: Cancer Screening and Early Detection
PPC: Primary Prevention of Cancer
DI: Dissemination of CPRIT-Funded Cancer Control Interventions

Cancer Prevention & Research
Institute of Texas

CEO Affidavit
Supporting Information

Academic Research Recruitment
FY 2025—Cycle 1
Recruitment of First-Time, Tenure-Track Faculty Members

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-25.1-RFT

Recruitment of First-Time, Tenure-Track Faculty Members

Please also refer to the Instructions for Applicants document, which will be posted on June 21, 2024

Application Receipt Dates:
June 21, 2024-June 20, 2025

FY 2025
Fiscal Year Award Period
September 1, 2024-August 31, 2025

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RFA VERSION HISTORY

6/21/24	RFA release
8/2/24	Modified language under Section 8.2.6: Letter of Support from Department Chair

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.

To accomplish CPRIT's long-term vision, the Oversight Committee has identified these 2025 priorities:

- Investing in the cancer research capacity of Texas institutions through recruitment of cancer scholars, investment in core facilities, and investment in individual investigator awards in all regions of the state;
- Building the Texas cancer life science ecosystem across Texas by bridging discovery and translational research into early-stage company products with high impact on cancer patient care and creating economic development for the State of Texas; and
- Increasing the capacity for Texas to have a significant impact on cancer prevention and early detection, ultimately decreasing cancer incidence and mortality.

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure in all regions of the state

- Reducing disparities in cancer incidence and mortality

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 and population research addressing cancer disparities
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer
- Expanding access to innovative clinical trials, particularly to regions of the state currently with limited access

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 and prevention 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, treatment, or survivorship. Principal Investigators (PIs) 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 oncology and analytic methods, research including population-based research addressing cancer disparities, childhood and adolescent 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 PIs 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. PIs 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 are encouraged.

Additionally, population research that addresses the burden of cancer in Texas is a priority for CPRIT. Applications nominating individuals who have demonstrated exceptional ability to lead innovative research programs involving any component across the continuum of cancer prevention and control research are appropriate for this mechanism and are highly 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 Member (RFTTFM) Award must therefore be complemented by a strong institutional commitment to the PI'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 8.2.5) and include the amount and sources of salary support and all additional financial support that will be available to the PI's research program through the course of the CPRIT award. The financial commitments made to the PI 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. Applicants are encouraged to tailor the budget as appropriate to the exigencies of the project; grant funds totaling less than $2,000,000 for the term of the award are acceptable if warranted by the scope of the research. Funding is to be used by the PI 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 PI or to construct or renovate laboratory space.

No annual limit on the number of grant application submissions for institutions has been set.

Note: In the event of insufficient funds, specific recruitment categories may be eliminated (example REI/RRS/RFTTFM) and nominations for specific categories may be closed for the remaining cycles of the fiscal year. Additionally, depending on the availability of funds, review cycles may be reduced, and/or the number of applications per institution may be capped, and recommended 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, 2025) or in the first quarter of the next fiscal year (starting September 1, 2025).

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.
- PIs 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 PI.
- A PI may be nominated by only 1 institution. If more than 1 institution is interested in a given PI, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.
- No annual limit on the number of grant submissions per institutions has been set.
- A PI who has already accepted a position as a tenure-track assistant professor at the recruiting institution prior to the time that the Scientific Review Council reviews the PI 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 PIs 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 PI 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 PI 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 PI must devote at least 70% effort to research activities. PIs whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the PI 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. PIs 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 PI 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 PI 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 PI will not be looked upon with favor.
- Successful PIs 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 RFTTFM Award mechanism. Any nomination for the RFTTFM Award 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. PIs 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 revised schedule for FY25 (See section 10 for RFA schedule).

For an application to be considered for review during the cycle, that application must be submitted on or before 11:59 PM central time on the 20th day of that cycle. In the event that the closing date 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. Nominators will be notified if this occurs. **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 (IFA) 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 PI's name, organization from which the PI is being recruited, and also the department and/or entity within the nominator's organization where the PI will hold the faculty position.

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

Provide a layperson's summary of the proposed work. **This section must be completed by the PI.** Describe, in simple, nontechnical terms, the overall aims 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 detection, prevention, treatment, or survivorship. 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.

8.2.3. Summary of Specific Aims and Sub Aims (2,000 characters)

Please provide a summary of the aims of the proposal. **This section must be completed by the PI.** The specific aims summary should identify the problem or gap in our current knowledge. It should present a hypothesis and briefly describe the aims and approaches and address the proposal's innovation, novel approaches, and significance and impact on the field and cancer research.

8.2.4. Specific Aims and Sub Aims

List specific aims and sub aims to be achieved during this award. **This section must be completed by the PI.** These aims/sub aims will also be used during the submission and evaluation of progress reports and assessment of project success. Refer to the template specific aims and sub aims document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.5. 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 RFTTFM Award must therefore be complemented by a strongly documented institutional commitment to the PI'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 PI:

- 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 PI's research program through the course of the CPRIT award. The

financial commitments made to the PI 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 PI. If an award dictates that such funds must be used for salary, the corresponding amount of institutional funds committed to pay the PI's salary will be redirected to allow the PI 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. Sources of support for the PI's full salary, including summer salary, for the duration of the award must be documented. If the PI is expected to provide salary support from grants during the award period, the institutional commitment must identify the source for salary support in the event grant support is not available. Note that a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the PI.
- Include a brief job description for the PI should recruitment be successful.
- Describe the institutional environment and any professional commitments to the PI 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 PI.
- Institutions may provide additional information in support of a PI's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a PI's cancer research. This additional information is highly encouraged when proposing a PI 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 PI.

Example of an acceptable Institutional Commitment table:

PI's Name, Institutional Commitments

	Year 1	Year 2	Year 3	Year 4	Year 5
*Salary/Benefits					
Research Support					
Administrative Support					
Moving Expenses					

Total =

***Sources of support for the PI's full salary, including summer salary, for the duration of the award must be documented.**

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

8.2.6. Letter of Support from Department Chair (up to 2 pages)

Provide the letter of support from and signed by the chair of the department to which the PI is being recruited. The following information should be included in the letter:

Recruitment Activities: CPRIT is committed to increasing the life sciences infrastructure in Texas via the recruitment of exceptional cancer researchers, as well as expanding research resources. The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this PI. Provide the necessary context by describing the institution's vision for the cancer programs, how the work of the nominee contributes to achieving these goals and the expected impact of the recruitment on the institution (or department) and the burden of cancer in Texas (if applicable).

Caliber of PI: The letter should include a description of the caliber of the PI and justification of the nomination of the PI by the institution. CPRIT recognizes that there is variability in the

metrics of impact applicable across the continuum of cancer research. For example, in some disciplines, research findings—although highly impactful on the field—are less likely to be published in the highest ranked journals, ie, *Science*, *Cell*, or *Nature* series. Thus, it is incumbent upon the institution to describe the impact of a nominee's work, including paradigm-shifting, practice-changing, or influence on public policy, population health behavior, or cancer disparities.

Description of PI Duties and Certification of 70% Effort to Research: While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the PI's effort must be committed to research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% level of effort will be dedicated to research must be included.

The letter of support from the department chair must also do the following:

1. Describe how the PI 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 PI.

8.2.7. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the PI. Only articles that have been published or that have been accepted for publication ("in press") should be cited.

8.2.8. Research (4 pages)

Summarize the key elements of the PI's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, specific aims, 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 PI. References cited in this section should be included in the Publications/References section (see 8.2.9).**

PIs 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."

8.2.9. Publications/References (1 page)

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

8.2.10. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a PI's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a PI's cancer research. This additional information is highly encouraged when proposing a PI 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).

8.2.11. Publications

Provide the 3 most significant publications that have resulted from the PI'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.

8.2.12. 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.

8.2.13. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the PI. If the PI 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.

8.2.14. Letters of Recommendation

Provide 3 letters of recommendation from individuals who are in a position to detail the PI's academic and scientific research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research.

8.2.15. Research Environment (1 page)

Clearly and concisely describe the research environment available to support the PI's research program, including core facilities, training programs, and collaborative opportunities.

8.2.16. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the PI, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the PI's specific aims, if selected, to receive the award. **This section of the application must be prepared by the PI.** If the application is approved for funding, this section will be made publicly available on CPRIT's website. PIs 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 be reviewed by the CPRIT Scientific Review Council according to the revised schedule (see section 10 for RFA schedule). Council members may seek additional ad hoc evaluations of PIs. 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 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 PI 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 PI. 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 PI agrees to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have an expectation that the recruitment will be successful if an award is granted by CPRIT. It is the expectation that the nominating institution provides CPRIT with a status of the award acceptance as soon as status is known.

Review criteria will focus on the overall impression of the PI, his or her proposed research program, and his or her long-term potential for contributions to, and impact on, the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the PI: Has the PI demonstrated academic excellence? Has the PI received excellent predoctoral and postdoctoral training? Does the PI show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the PI demonstrated a commitment to cancer research? Has the PI 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 PI's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term or address unique aspects of the burden of cancer in Texas? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Letters of Recommendation: Do the letters of recommendation detail the PI'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 PI's research? Is there evidence of strong institutional support? Will the PI 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 PI?

10. KEY DATES

RFA Schedule

RFA Release June 21, 2024

Review Cycle Dates

Review Cycle	Cycle Opens	Cycle Closes	Oversight Committee Review	Potential Award Date
25.1	6/21/24	8/20/24	11/20/24	12/1/24
25.2	8/21/24	10/21/24*	2/19/25	3/1/25
25.3	10/22/24	11/20/24	2/19/25	3/1/25
25.4	11/21/24	1/20/25	5/21/25	6/1/25
25.5	1/21/25	2/20/25	5/21/25	6/1/25
25.6	2/21/25	3/20/25	5/21/25	6/1/25
25.7	3/21/25	4/21/25*	8/20/25	8/31/25
25.8	4/22/25	5/20/25	8/20/25	8/31/25
25.9	5/21/25	6/20/25	8/20/25	8/31/25

*Cycle close extended due to the 20th falling on a Sunday

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 specific aims and address plans for the upcoming year. **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.

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.

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

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration, online submission of applications as well as page limitations, formatting, and how to upload application components/subsections in the appropriate tabs of CARS. Helpdesk staff cannot answer scientific or programmatic questions. Before contacting the Helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS.

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

Scientific and programmatic questions should be directed to the CPRIT Director of Academic Research. **Before contacting CPRIT, please refer to the *Instructions for Applicants* document and contact the Helpdesk for any items related to CARS, page limitations, formatting, etc.**

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

Third Party Observer Reports

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Academic Research Recruitment Review Panel-25.1 (25.1_REC_25.1)
Observation Report

Report No.	2024-09-12 25.1_REC_25.1
Program Name:	Academic Research
Panel Name:	25.1 Academic Research Recruitment Review Panel-25.1 (25.1 _REC_25.1)
Panel Date:	September 12, 2024
Report Date:	September 16, 2024

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 25.1 Academic Research Recruitment Review Panel-25.1 (25.1_REC_25.1) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on September 12, 2024.

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: Fourteen (14) application were discussed and six (6) applications were not discussed
- Panelists: One (1) panel chair, six (6) Ad-Hoc reviewers and six (6) 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: Three (3)
- 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, CRMA, 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 25.1
Awards Announced at the November 20, 2024, Oversight Committee Meeting

The following table lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment cycle 25.1 include those received in response to the following Requests for Applications: *Recruitment of First-Time, Tenure-Track Faculty Members*; *Recruitment of Established Investigators*; and *Recruitment of Rising Stars*.

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Principal Investigator	Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
No reported COIs.			
Applications not considered by the PIC or Oversight Committee:			
No reported COIs.			

De-Identified Overall Evaluation Scores

Recruitment of First-Time, Tenure-Track Faculty Members

Academic Research Recruitment Cycle 25.1

Application ID	Final Overall Evaluation Score
RR250017*	1.0
RR250052*	1.0
RR250002*	1.1
RR250014*	1.1
Aa	1.3
Ab	1.8
Ac	2.0
Ad	2.7
Ae	3.1
Af	3.5
Ag	3.5
Ah	3.5
Ai	3.6
Aj	6.0

* Recommended for funding.

Final Overall Evaluation Scores and Rank Order Scores

UC San Diego
SCHOOL OF MEDICINE

October 16, 2024

Dr. David A. Cummings, M.D.
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dcummingsmd@yahoo.com

Ms. Kristen Doyle
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to kdoyle@cprit.texas.gov

Dear Dr. Cummings and Ms. Doyle,

The Scientific Review Council (SRC) is pleased to submit this list of five Recruitment grant recommendations for the Recruitment of Rising Stars and Recruitment of First-Time, Tenure-Track Faculty Members.

The SRC met on September 12, 2024, to review Recruitment of Established Investigators, Rising Start and First-Time Tenure-Track Faculty Members applications submitted for Cycle FY2025.1

Recommended funding amounts and the overall evaluation score are stated for each grant application in the following table. The total amount for the applications recommended to the PIC is $12,000,000.

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

Department of Cellular and Molecular Medicine
UC San Diego School of Medicine • 9500 Gilman Drive, Mail Code 0660 • La Jolla, CA 92093-0660
T: 858-534-7804 • F: 858-534-7750 • rkolodner@health.ucsd.edu

UC San Diego
SCHOOL OF MEDICINE

Rank	ID	RFA	Application Title	PI	PI Org.	Rec. Budget	Score
1	RR250017	RFTFM	Targeting Membrane Enzymes by Structure-Based Drug Discovery for Pancreatic Ductal Adenocarcinoma	Fangyu Liu, Ph.D.	The University of Texas Southwestern Medical Center	$ 2,000,000.00	**1.0**
2	RR250052	RFTFM	Harnessing Protein Translation Machinery to Overcome Resistance of KRAS Inhibitors	Xiangdong Lv, Ph. D	The University of Texas Health Science Center at Houston	$ 2,000,000.00	**1.0**
3	RR250002	RFTFM	Dissecting Niche Cells in Cancer Immunity and Metastasis	Norihiro Goto, M.D., Ph.D.	The University of Texas M. D. Anderson Cancer Center	$ 2,000,000.00	**1.1**
4	RR250014	RFTFM	Decoding the Immune Network Dynamics in Acute Myeloid Leukemia	Xufeng Chen, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$ 2,000,000.00	**1.1**
5	RR250048	RRS	Novel clinical biomarkers and mechanisms of Cardiotoxicity	Daniel Addison, M.D.	The University of Texas Southwestern Medical Center	$ 4,000,000.00	**1.1**

Recruitment of Rising Stars
Recruitment of First-Time, Tenure Track Faculty Members (RFTTFM)

Department of Cellular and Molecular Medicine
UC San Diego School of Medicine • 9500 Gilman Drive, Mail Code 0660 • La Jolla, CA 92093-0660
T: 858-534-7804 • F: 858-534-7750 • rkolodner@health.ucsd.edu

Cancer Prevention & Research
Institute of Texas

CEO Affidavit
Supporting Information

Academic Research Recruitment
FY 2025—Cycle 1
Recruitment of Rising Stars

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-25.1-RRS

Recruitment of Rising Stars

Please also refer to the Instructions for Applicants document, which will be posted on June 21, 2024

Application Receipt Dates:
June 21, 2024-June 20, 2025

FY 2025
Fiscal Year Award Period
September 1, 2024-August 31, 2025

TABLE OF CONTENTS

RFA VERSION HISTORY

6/21/24	RFA release
8/2/24	Modified language under Section 8.2.6: Letter of Support from Department Chair

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.

To accomplish CPRIT's long-term vision, the Oversight Committee has identified these 2025 priorities:

- Investing in the cancer research capacity of Texas institutions through recruitment of cancer scholars, investment in core facilities, and investment in individual investigator awards in all regions of the state;
- Building the Texas cancer life science ecosystem across Texas by bridging discovery and translational research into early-stage company products with high impact on cancer patient care and creating economic development for the State of Texas; and
- Increasing the capacity for Texas to have a significant impact on cancer prevention and early detection, ultimately decreasing cancer incidence and mortality.

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure in all regions of the state

- Reducing disparities in cancer incidence and mortality

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 and population research addressing cancer disparities.
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer
- Expanding access to innovative clinical trials, particularly to regions of the state currently with limited access.

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract individuals whose work has outstanding merit, who show a marked capacity for self-direction, and who demonstrate the promise for continued and enhanced contributions to the field of cancer research ("Rising Stars"). Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research and prevention 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, treatment, or survivorship. Principal Investigators (PIs) 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, research including population-based research, computational oncology and

analytic methods, childhood and adolescent 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. Having already demonstrated extraordinary accomplishments during their initial years of independent research, Rising Stars represent a unique blend of scholastic aptitude, scientific rigor, and commitment to exploring transformational research through the development of creative ideas with high potential.

PIs who have not historically worked in cancer research but are proposing creative hypotheses and research plans for this field are encouraged to apply. Similarly, PIs pursuing original and potentially high-impact basic science programs that have the potential to be translated toward clinical investigations or provide "proof of principle" are also encouraged to apply. It is expected that the PI will contribute significantly to, and have a major impact on, the institution's overall cancer research initiative. Funding will be given for exceptional PIs who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal PIs will have specific expertise in cancer-related areas needed to address an institutional priority. PIs are expected to be approximately at the career level of a late assistant/early associate professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Applications nominating individuals who carry out patient-oriented research and who have demonstrated exceptional ability to lead innovative discovery campaigns through conduct of clinical trials are appropriate for this mechanism and are encouraged.

Additionally, population research that addresses the burden of cancer in Texas is a priority for CPRIT. Applications nominating individuals who have demonstrated exceptional ability to lead

innovative research programs involving any component across the continuum of cancer prevention and control research are appropriate for this mechanism and are highly encouraged.

Applications that include purposeful collaborations with institutions eligible for a CPRIT Texas Regional Excellence in Cancer Award are highly 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 Rising Star (RRS) Award must be complemented by a strong institutional commitment to the recruitment. The institutional commitment should be clearly documented in the application (see section 8.2.5) and include the amount and sources of salary support and all additional financial support that will be available to the PI's research program through the course of the CPRIT award. The financial commitments made to the PI 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 is a 5-year award and is not renewable. Grant funds of up to $4,000,000 (total costs) over a 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. Annual allocations of this award are at the discretion of the awardee as long as the total award does not exceed $4,000,000. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years except under extraordinary circumstances with strong justification for a no-

cost extension. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified 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 award mechanism may be used for salary support of this PI but may not be used to construct or renovate laboratory space.

No annual limit on the number of grant application submissions for institutions has been set.

Note that the annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award for FY 2025 is limited to a maximum of $225,000. In other words, an individual may request salary proportional to the percent of effort up to a maximum of $225,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

Note: In the event of insufficient funds, specific recruitment categories may be eliminated (example: REI/RRS/RFTTFM) and nominations for specific categories may be closed for the remaining cycles of the fiscal year. Additionally, depending on the availability of funds, review cycles may be reduced, and/or the number of applications per institution may be capped, and recommended 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, 2025) or in the first quarter of the next fiscal year (starting September 1, 2025).

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.
- PIs 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 PI.

- A PI may be nominated by only 1 institution. If more than 1 institution is interested in a given PI, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.
- No annual limit on the number of grant submissions per institution has been set
- A PI who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council reviews the PI 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 PIs 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 PI 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 PI 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 PI must devote at least 70% effort to research activities. PIs whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the PI should hold an appointment at the rank of assistant or associate professor tenure track or tenured (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation. The PI must not reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.

- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member, or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Resubmissions will not be accepted for the RRS Award mechanism. Any nomination for the RRS Award that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. A nomination for the RRS Award that was previously submitted to CPRIT for the Recruitment of First-Time, Tenure Track Faculty Member or RRS Award and reviewed and recommended for funding but declined by the PI may be submitted in response to this RFA if the PI meets the eligibility criteria described in section 6 and the application is not in the same fiscal year as the previous application. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles. Applications being resubmitted according to the criteria permitted by this section should be submitted as a new application (refer to the Instructions for Applicants [IFA] for more details).

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. PIs 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 revised schedule for FY25 (See section 10 for RFA schedule).

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 on the 20th day of that cycle. 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. Nominators will be notified if this occurs. **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 (2,500 characters)

Provide a brief summary of the nomination. Include the PI's name, organization from which the PI is being recruited, and also the department and/or entity within the nominator's organization where the PI will hold the faculty position.

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

Provide a layperson's summary of the proposed work. **This section must be completed by the PI.** Describe, in simple, nontechnical terms, the overall aims 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 detection, prevention, treatment, or survivorship. 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.

8.2.3. Summary of Specific Aims and Sub-Aims (2,000 characters)

Please provide a summary of the aims of the proposal. **This section must be completed by the PI.** The specific aims summary should identify the problem or gap in our current knowledge. It should present a hypothesis and briefly describe the aims and approaches and address the proposal's innovation, novel approaches, and significance and impact on the field and cancer research.

8.2.4. Specific Aims and Sub-Aims

List Specific Aims and SubAims to be achieved during this award. **This section must be completed by the PI.** These aims/subaims will also be used during the submission and evaluation of progress reports and assessment of project success. Refer to the template for specific aims and subaims document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.5. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a Rising Stars PI must be complemented by a strongly documented

institutional commitment to the recruitment. The financial commitments made to the PI 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 following guidelines should be followed when documenting the institutional commitment to the PI:

- 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 PI's research program through the course of the CPRIT award. The financial commitments made to the PI 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 an investigator-initiated award received by the PI. If an award dictates that such funds must be used for salary, the corresponding amount of institutional funds committed to pay the PI's salary will be redirected to allow the PI 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. Sources of support for the PI's full salary, including summer salary, for the duration of the award must be documented. If the PI is expected to provide salary support from grants during the award period, the institutional commitment must identify the source for salary support in the event grant support is not available. Note that a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the PI.
- Include a brief job description of the PI should recruitment be successful.
- Describe the institutional environment and any professional commitments to the PI 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 PI.

- Institutions may provide additional information in support of a PI's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a PI's cancer research. This additional information is highly encouraged when proposing a PI 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 PI.

Example of an acceptable Institutional Commitment table:

PI's Name, Institutional Commitments

	Year 1	Year 2	Year 3	Year 4	Year 5
Salary/Benefits*					
Research Support					
Administrative Support					
Moving Expenses					

Total =

*** Sources of support for the PI's full salary, including summer salary, for the duration of the award must be documented.**

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

8.2.6. Letter of Support from Department Chair (up to 2 pages)

Provide the letter of support from and signed by the chair of the department to which the PI is being recruited. The following information should be included in the letter:

Recruitment Activities: CPRIT is committed to increasing the life sciences infrastructure in Texas via the recruitment of exceptional cancer researchers, as well as expanding research resources. The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this PI. Provide the necessary context by describing the institution's vision for the cancer programs, how the work of the nominee contributes to achieving these goals and the expected impact of the recruitment on the institution (or department) and the burden of cancer in Texas (if applicable).

Caliber of PI: The letter should include a description of the caliber of the PI and justification of nomination of the PI by the institution. CPRIT recognizes that there is variability in the metrics of impact applicable across the continuum of cancer research. For example, in some disciplines, research findings—although highly impactful on the field—are less likely to be published in the highest ranked journals, ie, *Science*, *Cell*, or *Nature* series. Thus, it is incumbent on the institution to describe the impact of a nominee's work, including paradigm-shifting, practice-changing, or influence on public policy, population health behavior, or cancer disparities.

Description of PI Duties and Certification of 70% Effort to Research: While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the PI's effort must be committed to research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% level of effort will be dedicated to research must be included.

8.2.7. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the PI.

8.2.8. Research (4 pages)

Summarize the key elements of the PI'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 PI. References cited in this section should be included in the Publications/References Section (see 8.2.9).**

PIs 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."

8.2.9. Publications/References (1 Page)

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

8.2.10. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a PI's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a PI's cancer research. This additional information is highly encouraged when proposing a PI 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).

8.2.11. Publications

Provide the 5 most significant publications that have resulted from the PI'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.

8.2.12. 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.

8.2.13. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the PI. If the PI 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.

8.2.14. Research Environment (1 page)

Briefly describe the research environment available to support the PI's research program, including core facilities, training programs, and collaborative opportunities.

8.2.15. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the PI, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the PI's goals if selected to receive the award. **This section of the application must be prepared by the PI.** If the application is approved for funding, this section will be made publicly available on CPRIT's website. PIs 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 (see Section 10 for schedule). Council members may seek additional ad hoc evaluations of PIs. 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, in 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 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 PI 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 PI. Recruitment efforts are not likely to be successful unless there is a strong commitment from CPRIT and the host institution.** It is not necessary that a PI agrees to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have an expectation that the recruitment will be successful if an award is granted by CPRIT. It is the expectation that the nominating institution provides CPRIT with a status of the award acceptance as soon as status is known.

Review criteria will focus on the overall impression of the PI, his/her proposed research program, and his/her long-term contribution to, and impact on, the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the PI: Has the PI demonstrated extraordinary accomplishments during his or her initial years of independent research? Does the PI show promise of making important contributions with significant impact to basic, translational, clinical, or population-based cancer research in the future? Has the PI demonstrated strong self-direction, motivation, and commitment for transformative cancer research?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will it expand the boundaries of

cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques?

Relevance of PI's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term, or address unique aspects of the burden of cancer in Texas. Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the PI's research? Is there evidence of strong institutional support? Will the PI be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program? Will the PI be provided with adequate professional development opportunities to grow as a leader?

10. KEY DATES

RFA Schedule

RFA Release June 21, 2024

Review Cycle Dates

Review Cycle	Cycle Opens	Cycle Closes	Oversight Committee Review	Potential Award Date
25.1	6/21/24	8/20/24	11/20/24	12/1/24
25.2	8/21/24	10/21/24*	2/19/25	3/1/25
25.3	10/22/24	11/20/24	2/19/25	3/1/25
25.4	11/21/24	1/20/25	5/21/25	6/1/25
25.5	1/21/25	2/20/25	5/21/25	6/1/25
25.6	2/21/25	3/20/25	5/21/25	6/1/25
25.7	3/21/25	4/21/25*	8/20/25	8/31/25
25.8	4/22/25	5/20/25	8/20/25	8/31/25
25.9	5/21/25	6/20/25	8/20/25	8/31/25

*Cycle close extended due to the 20th falling on a Sunday

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 aims and address plans for the upcoming year. **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.

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.

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

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration, online submission of applications as well as page limitations, formatting, and how to upload application components/subsections in the appropriate tabs of CARS. Helpdesk staff cannot answer scientific or programmatic questions. Before contacting the Helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS.

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

Scientific and programmatic questions should be directed to the CPRIT Director of Academic Research. **Before contacting CPRIT, please refer to the *Instructions for Applicants* document and contact the Helpdesk for any items related to CARS, page limitations, formatting, etc.**

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

Third Party Observer Reports

BFS STRATEGIC PARTNERS

Cancer Prevention and Research Institute of Texas (CPRIT)
25.1 Academic Research Recruitment Review Panel-25.1 (25.1_REC_25.1)
Observation Report

Report No.	2024-09-12 25.1_REC_25.1
Program Name:	Academic Research
Panel Name:	25.1 Academic Research Recruitment Review Panel-25.1 (25.1 _REC_25.1)
Panel Date:	September 12, 2024
Report Date:	September 16, 2024

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 25.1 Academic Research Recruitment Review Panel-25.1 (25.1_REC_25.1) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on September 12, 2024.

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: Fourteen (14) application were discussed and six (6) applications were not discussed
- Panelists: One (1) panel chair, six (6) Ad-Hoc reviewers and six (6) 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: Three (3)
- 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, CRMA, 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 25.1
Awards Announced at the November 20, 2024, Oversight Committee Meeting

The following table lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment cycle 25.1 include those received in response to the following Requests for Applications: *Recruitment of First-Time, Tenure-Track Faculty Members*; *Recruitment of Established Investigators*; and *Recruitment of Rising Stars*.

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Principal Investigator	Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
No reported COIs.			
Applications not considered by the PIC or Oversight Committee:			
No reported COIs.			

De-Identified Overall Evaluation Scores

Recruitment of Rising Stars

Academic Research Recruitment Cycle 25.1

Application ID	Final Overall Evaluation Score
RR250048*	1.1
Ba	1.5
Bb	2.9
Bc	3.5
Bd	4.0

* Recommended for funding.

Final Overall Evaluation Scores and Rank Order Scores

UC San Diego
SCHOOL OF MEDICINE

October 16, 2024

Dr. David A. Cummings, M.D.
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to dcummingsmd@yahoo.com

Ms. Kristen Doyle
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to kdoyle@cprit.texas.gov

Dear Dr. Cummings and Ms. Doyle,

The Scientific Review Council (SRC) is pleased to submit this list of five Recruitment grant recommendations for the Recruitment of Rising Stars and Recruitment of First-Time, Tenure-Track Faculty Members.

The SRC met on September 12, 2024, to review Recruitment of Established Investigators, Rising Start and First-Time Tenure-Track Faculty Members applications submitted for Cycle FY2025.1

Recommended funding amounts and the overall evaluation score are stated for each grant application in the following table. The total amount for the applications recommended to the PIC is $12,000,000.

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

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T: 858-534-7804 • F: 858-534-7750 • rkolodner@health.ucsd.edu

UC San Diego
SCHOOL OF MEDICINE

Rank	ID	RFA	Application Title	PI	PI Org.	Rec. Budget	Score
1	RR250017	RFTFM	Targeting Membrane Enzymes by Structure-Based Drug Discovery for Pancreatic Ductal Adenocarcinoma	Fangyu Liu, Ph.D.	The University of Texas Southwestern Medical Center	$ 2,000,000.00	**1.0**
2	RR250052	RFTFM	Harnessing Protein Translation Machinery to Overcome Resistance of KRAS Inhibitors	Xiangdong Lv, Ph. D	The University of Texas Health Science Center at Houston	$ 2,000,000.00	**1.0**
3	RR250002	RFTFM	Dissecting Niche Cells in Cancer Immunity and Metastasis	Norihiro Goto, M.D., Ph.D.	The University of Texas M. D. Anderson Cancer Center	$ 2,000,000.00	**1.1**
4	RR250014	RFTFM	Decoding the Immune Network Dynamics in Acute Myeloid Leukemia	Xufeng Chen, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$ 2,000,000.00	**1.1**
5	RR250048	RRS	Novel clinical biomarkers and mechanisms of Cardiotoxicity	Daniel Addison, M.D.	The University of Texas Southwestern Medical Center	$ 4,000,000.00	**1.1**

Recruitment of Rising Stars
Recruitment of First-Time, Tenure Track Faculty Members (RFTTFM)

Department of Cellular and Molecular Medicine
UC San Diego School of Medicine • 9500 Gilman Drive, Mail Code 0660 • La Jolla, CA 92093-0660
T: 858-534-7804 • F: 858-534-7750 • rkolodner@health.ucsd.edu

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP250135
Texas Therapeutics Company Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 Therapeutics Company Awards* Request for Applications (RFA). CPRIT received 21 preliminary applications in response to this RFA, including one withdrawn application. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-22. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Pursuant to the approved communication waiver, Dr. Smith negotiated a reduced overall budget with the grant applicant. At the PIC meeting on November 6, Dr. Smith presented this application with the negotiated budget. The PIC unanimously recommended the application to the Oversight Committee with the lower overall budget.

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Texas Therapeutics Company Full Awards for Product Development Research
APPLICATION ID: DP250135
APPLICATION TITLE: Personalized Immunotherapy for Recurrent, Resectable Head and Neck Cancer
APPLICANT NAME: Pack, Christopher D
ORGANIZATION: Metaclipse Therapeutics Corporation
PANEL NAME: 25.1 Product Development Panel-22

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**07/25/2024**	09/30/2024
	Method of submission	**CARS**	09/30/2024
	Within receipt period	**YES**	09/30/2024
	Request for extension to submit application after CARS closed	**N/A**	09/30/2024
	Request for extension for late application submission accepted	**N/A**	09/30/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	09/30/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/30/2024
	Assigned to primary reviewers	**08/02/2024**	09/30/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/30/2024
	Primary Reviewer 1 COI signed	**07/26/2024**	09/30/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/26/2024**	09/30/2024
	Primary Reviewer 3 COI signed	**07/29/2024**	09/30/2024
	Primary Reviewer 4 COI signed	**07/26/2024**	09/30/2024
	Primary Reviewer 5 COI signed	**07/28/2024**	09/30/2024
	Primary Reviewer 6 COI signed	**07/27/2024**	09/30/2024
	Primary Reviewer 7 COI signed	**07/27/2024**	09/30/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/07/2024**	09/30/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/08/2024**	09/30/2024
	Primary Reviewer 3 critique submitted	**08/12/2024**	09/30/2024
	Primary Reviewer 4 critique submitted	**08/24/2024**	09/30/2024
	Primary Reviewer 5 critique submitted	**08/25/2024**	09/30/2024
	Primary Reviewer 6 critique submitted	**08/13/2024**	09/30/2024
	Primary Reviewer 7 critique submitted	**08/14/2024**	09/30/2024
	COI indicated by non-primary reviewer	**NONE**	09/30/2024
	COI recused from participation	**N/A**	09/30/2024
	Peer Review Meeting	**09/27/2024**	09/30/2024
	Post review statements signed	**09/27/2024**	09/30/2024
	Third Party Observer Report	**10/01/2024**	10/03/2024
	Score report delivered to CPDO	**09/30/2024**	09/30/2024
	Recommended for due diligence and IP review	**YES**	09/30/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/11/2024**	11/04/2024
	Final intellectual property review submitted	**10/11/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Meeting	**10/21/2024**	10/29/2024
	Third Party Observer Report	**10/23/2024**	10/29/2024
	Recommended for grant award	**YES**	10/29/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 DP250137
SEED Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *SEED Awards for Product Development Research* Request for Applications (RFA). CPRIT received 47 preliminary applications in response to this RFA, including three preliminary applications that were withdrawn. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-6. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Pursuant to the approved communication waiver, Dr. Smith negotiated a reduced overall budget with the grant applicant. At the PIC meeting on November 6, Dr. Smith presented this application with the negotiated budget. The PIC unanimously recommended the application to the Oversight Committee with the lower overall budget.

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Seed Full Awards for Product Development Research
APPLICATION ID: DP250137
APPLICATION TITLE: Revolutionizing Solid Tumor Therapy with Bispecific TCRm Antibodies Targeting Intracellular Cancer Targets
APPLICANT NAME: Zha, Dongxing
ORGANIZATION: Ypsilon Therapeutics
PANEL NAME: 25.1 Product Development Panel-6

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**07/23/2024**	09/18/2024
	Method of submission	**CARS**	09/18/2024
	Within receipt period	**YES**	09/18/2024
	Request for extension to submit application after CARS closed	**N/A**	09/18/2024
	Request for extension for late application submission accepted	**N/A**	09/18/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	09/18/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/18/2024
	Assigned to primary reviewers	**08/01/2024**	09/18/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/18/2024
	Primary Reviewer 1 COI signed	**07/26/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/28/2024**	09/18/2024
	Primary Reviewer 3 COI signed	**07/29/2024**	09/18/2024
	Primary Reviewer 4 COI signed	**08/08/2024**	09/18/2024
	Primary Reviewer 5 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 6 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 7 COI signed	**07/27/2024**	09/18/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/25/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/26/2024**	09/18/2024
	Primary Reviewer 3 critique submitted	**08/26/2024**	09/18/2024
	Primary Reviewer 4 critique submitted	**08/25/2024**	09/18/2024
	Primary Reviewer 5 critique submitted	**08/27/2024**	09/18/2024
	Primary Reviewer 6 critique submitted	**08/18/2024**	09/18/2024
	Primary Reviewer 7 critique submitted	**08/25/2024**	09/18/2024
	COI indicated by non-primary reviewer	**NONE**	09/18/2024
	COI recused from participation	**N/A**	09/18/2024
	Peer Review Meeting	**09/12/2024**	09/18/2024
	Post review statements signed	**09/12/2024**	09/18/2024
	Third Party Observer Report	**09/16/2024**	09/18/2024
	Score report delivered to CPDO	**09/13/2024**	09/18/2024
	Recommended for due diligence and IP review	**YES**	09/18/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/11/2024**	11/04/2024
	Final intellectual property review submitted	**10/07/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/18/2024
	COI recused from participation	**N/A**	10/18/2024
	Due Diligence Meeting	**10/15/2024**	10/18/2024
	Third Party Observer Report	**10/17/2024**	10/22/2024
	Recommended for grant award	**YES**	10/18/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 DP250140
Texas Therapeutics Company Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 Therapeutics Company Awards* Request for Applications (RFA). CPRIT received 21 preliminary applications in response to this RFA, including one withdrawn application. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-7. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

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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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Texas Therapeutics Company Full Awards for Product Development Research
APPLICATION ID: DP250140
APPLICATION TITLE: A Phase 1 clinical trial of OR-449, a novel oral targeted therapy for pediatric and adult adrenocortical cancer patients
APPLICANT NAME: Thacher, Scott M
ORGANIZATION: Orphagen Pharmaceuticals, Inc.
PANEL NAME: 25.1 Product Development Panel-7

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**07/25/2024**	09/18/2024
	Method of submission	**CARS**	09/18/2024
	Within receipt period	**YES**	09/18/2024
	Request for extension to submit application after CARS closed	**N/A**	09/18/2024
	Request for extension for late application submission accepted	**N/A**	09/18/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	09/18/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/18/2024
	Assigned to primary reviewers	**08/01/2024**	09/18/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/18/2024
	Primary Reviewer 1 COI signed	**07/26/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 3 COI signed	**07/29/2024**	09/18/2024
	Primary Reviewer 4 COI signed	**07/28/2024**	09/18/2024
	Primary Reviewer 5 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 6 COI signed	**07/28/2024**	09/18/2024
	Primary Reviewer 7 COI signed	**07/26/2024**	09/18/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/23/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/23/2024**	09/18/2024
	Primary Reviewer 3 critique submitted	**08/26/2024**	09/18/2024
	Primary Reviewer 4 critique submitted	**08/26/2024**	09/18/2024
	Primary Reviewer 5 critique submitted	**08/25/2024**	09/18/2024
	Primary Reviewer 6 critique submitted	**08/27/2024**	09/18/2024
	Primary Reviewer 7 critique submitted	**08/25/2024**	09/18/2024
	COI indicated by non-primary reviewer	**NONE**	09/18/2024
	COI recused from participation	**N/A**	09/18/2024
	Peer Review Meeting	**09/13/2024**	09/18/2024
	Post review statements signed	**09/13/2024**	09/18/2024
	Third Party Observer Report	**09/18/2024**	09/24/2024
	Score report delivered to CPDO	**09/13/2024**	09/18/2024
	Recommended for due diligence and IP review	**YES**	09/18/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/09/2024**	11/04/2024
	Final intellectual property review submitted	**10/03/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/18/2024
	COI recused from participation	**N/A**	10/18/2024
	Due Diligence Meeting	**10/14/2024**	10/18/2024
	Third Party Observer Report	**10/17/2024**	10/22/2024
	Recommended for grant award	**YES**	10/18/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 DP250142
Texas Therapeutics Company Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 Therapeutics Company Awards* Request for Applications (RFA). CPRIT received 21 preliminary applications in response to this RFA, including one withdrawn application. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-9. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Pursuant to the approved communication waiver, Dr. Smith negotiated a reduced overall budget with the grant applicant. At the PIC meeting on November 6, Dr. Smith presented this application with the negotiated budget. The PIC unanimously recommended the application to the Oversight Committee with the lower overall budget.

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Texas Therapeutics Company Full Awards for Product Development Research
APPLICATION ID: DP250142
APPLICATION TITLE: Eisbach Bio - Clinical Development of the ALC1 DDR inhibitor EIS-12656
APPLICANT NAME: Schomburg, Adrian
ORGANIZATION: Eisbach Bio Inc.
PANEL NAME: 25.1 Product Development Panel-9

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**07/24/2024**	09/18/2024
	Method of submission	**CARS**	09/18/2024
	Within receipt period	**YES**	09/18/2024
	Request for extension to submit application after CARS closed	**N/A**	09/18/2024
	Request for extension for late application submission accepted	**N/A**	09/18/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**07/31/2024**	09/18/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/18/2024
	Assigned to primary reviewers	**08/01/2024**	09/18/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/18/2024
	Primary Reviewer 1 COI signed	**07/31/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/28/2024**	09/18/2024
	Primary Reviewer 3 COI signed	**07/27/2024**	09/18/2024
	Primary Reviewer 4 COI signed	**07/29/2024**	09/18/2024
	Primary Reviewer 5 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 6 COI signed	**07/29/2024**	09/18/2024
	Primary Reviewer 7 COI signed	**07/26/2024**	09/18/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**10/02/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/26/2024**	09/18/2024
	Primary Reviewer 3 critique submitted	**08/15/2024**	09/18/2024
	Primary Reviewer 4 critique submitted	**08/22/2024**	09/18/2024
	Primary Reviewer 5 critique submitted	**08/20/2024**	09/18/2024
	Primary Reviewer 6 critique submitted	**08/27/2024**	09/18/2024
	Primary Reviewer 7 critique submitted	**08/25/2024**	09/18/2024
	COI indicated by non-primary reviewer	**NONE**	09/18/2024
	COI recused from participation	**N/A**	09/18/2024
	Peer Review Meeting	**09/16/2024**	09/18/2024
	Post review statements signed	**09/16/2024**	09/18/2024
	Third Party Observer Report	**09/18/2024**	09/24/2024
	Score report delivered to CPDO	**09/16/2024**	09/18/2024
	Recommended for due diligence and IP review	**YES**	09/18/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/09/2024**	11/04/2024
	Final intellectual property review submitted	**10/03/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/18/2024
	COI recused from participation	**N/A**	10/18/2024
	Due Diligence Meeting	**10/14/2024**	10/18/2024
	Third Party Observer Report	**10/17/2024**	10/22/2024
	Recommended for grant award	**YES**	10/18/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 DP250143
SEED Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *SEED Awards for Product Development Research* Request for Applications (RFA). CPRIT received 47 preliminary applications in response to this RFA, including three preliminary applications that were withdrawn. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-12. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Pursuant to the approved communication waiver, Dr. Smith negotiated a reduced overall budget with the grant applicant. At the PIC meeting on November 6, Dr. Smith presented this application with the negotiated budget. The PIC unanimously recommended the application to the Oversight Committee with the lower overall budget.

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Seed Full Awards for Product Development Research
APPLICATION ID: DP250143
APPLICATION TITLE: TELOVANCE: A Transient Telomere Lengthening Platform Designed to Enhance the Expansion and Efficacy of Human Cell and Gene Therapies
APPLICANT NAME: SAYED, MOHAMMAD E
ORGANIZATION: Telos Biotechnology
PANEL NAME: 25.1 Product Development Panel-12

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**07/12/2024**	09/23/2024
	Method of submission	**CARS**	09/23/2024
	Within receipt period	**YES**	09/23/2024
	Request for extension to submit application after CARS closed	**N/A**	09/23/2024
	Request for extension for late application submission accepted	**N/A**	09/23/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**07/31/2024**	09/23/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/23/2024
	Assigned to primary reviewers	**08/01/2024**	09/23/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/23/2024
	Primary Reviewer 1 COI signed	**07/26/2024**	09/23/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/26/2024**	09/23/2024
	Primary Reviewer 3 COI signed	**07/26/2024**	09/23/2024
	Primary Reviewer 4 COI signed	**07/30/2024**	09/23/2024
	Primary Reviewer 5 COI signed	**07/26/2024**	09/23/2024
	Primary Reviewer 6 COI signed	**08/08/2024**	09/23/2024
	Primary Reviewer 7 COI signed	**07/27/2024**	09/23/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/12/2024**	09/23/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/25/2024**	09/23/2024
	Primary Reviewer 3 critique submitted	**08/28/2024**	09/23/2024
	Primary Reviewer 4 critique submitted	**08/26/2024**	09/23/2024
	Primary Reviewer 5 critique submitted	**08/25/2024**	09/23/2024
	Primary Reviewer 6 critique submitted	**08/26/2024**	09/23/2024
	Primary Reviewer 7 critique submitted	**08/24/2024**	09/23/2024
	COI indicated by non-primary reviewer	**NONE**	09/23/2024
	COI recused from participation	**N/A**	09/23/2024
	Peer Review Meeting	**09/17/2024**	09/23/2024
	Post review statements signed	**09/17/2024**	09/23/2024
	Third Party Observer Report	**09/20/2024**	09/24/2024
	Score report delivered to CPDO	**09/18/2024**	09/23/2024
	Recommended for due diligence and IP review	**YES**	09/23/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/11/2024**	11/04/2024
	Final intellectual property review submitted	**10/08/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	Due Diligence Meeting	**10/16/2024**	10/21/2024
	Third Party Observer Report	**10/17/2024**	10/22/2024
	Recommended for grant award	**YES**	10/21/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 DP250149
SEED Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *SEED Awards for Product Development Research* Request for Applications (RFA). CPRIT received 47 preliminary applications in response to this RFA, including three preliminary applications that were withdrawn. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-20. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Pursuant to the approved communication waiver, Dr. Smith negotiated a reduced overall budget with the grant applicant. At the PIC meeting on November 6, Dr. Smith presented this application with the negotiated budget. The PIC unanimously recommended the application to the Oversight Committee with the lower overall budget.

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Seed Full Awards for Product Development Research
APPLICATION ID: DP250149
APPLICATION TITLE: Functional assay of immunoproteasome for patient stratification to checkpoint inhibitor therapy using single-molecule protein sequencing
APPLICANT NAME: Swaminathan, Jagannath
ORGANIZATION: Erisyon, INC
PANEL NAME: 25.1 Product Development Panel-20

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**08/01/2024**	09/27/2024
	Method of submission	**CARS**	09/27/2024
	Within receipt period	**NO**	09/27/2024
	Request for extension to submit application after CARS closed	**N/A**	09/27/2024
	Request for extension for late application submission accepted	**N/A**	09/27/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**07/31/2024**	09/27/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/27/2024
	Assigned to primary reviewers	**08/02/2024**	09/27/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/27/2024
	Primary Reviewer 1 COI signed	**07/26/2024**	09/27/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/26/2024**	09/27/2024
	Primary Reviewer 3 COI signed	**07/26/2024**	09/27/2024
	Primary Reviewer 4 COI signed	**07/31/2024**	09/27/2024
	Primary Reviewer 5 COI signed	**07/29/2024**	09/27/2024
	Primary Reviewer 6 COI signed	**07/26/2024**	09/27/2024
	Primary Reviewer 7 COI signed	**07/28/2024**	09/27/2024
	Primary Reviewer 8 COI signed	**07/27/2024**	09/27/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/26/2024**	09/27/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/23/2024**	09/27/2024
	Primary Reviewer 3 critique submitted	**08/24/2024**	09/27/2024
	Primary Reviewer 4 critique submitted	**08/27/2024**	09/27/2024
	Primary Reviewer 5 critique submitted	**08/25/2024**	09/27/2024
	Primary Reviewer 6 critique submitted	**08/26/2024**	09/27/2024
	Primary Reviewer 7 critique submitted	**08/26/2024**	09/27/2024
	Primary Reviewer 8 critique submitted	**08/18/2024**	09/27/2024
	COI indicated by non-primary reviewer	**NONE**	09/27/2024
	COI recused from participation	**N/A**	09/27/2024
	Peer Review Meeting	**09/26/2024**	09/27/2024
	Post review statements signed	**09/26/2024**	09/27/2024
	Third Party Observer Report	**10/01/2024**	10/23/2024
	Score report delivered to CPDO	**09/26/2024**	09/27/2024
	Recommended for due diligence and IP review	**YES**	09/27/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/09/2024**	11/04/2024
	Final intellectual property review submitted	**10/10/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	Due Diligence Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	10/23/2024
	Recommended for grant award	**YES**	10/21/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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
CPRIT agreed to re-open CARS on 8/1/2024 from 1:00pm to 3:00pm CT to allow the applicant to revise their budget.	**2024-09-27 13:32:06.09**

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP250150
Texas Therapeutics Company Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 Therapeutics Company Awards* Request for Applications (RFA). CPRIT received 21 preliminary applications in response to this RFA, including one withdrawn application. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-2. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Pursuant to the approved communication waiver, Dr. Smith negotiated a reduced overall budget with the grant applicant. At the PIC meeting on November 6, Dr. Smith presented this application with the negotiated budget. The PIC unanimously recommended the application to the Oversight Committee with the lower overall budget.

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Texas Therapeutics Company Full Awards for Product Development Research
APPLICATION ID: DP250150
APPLICATION TITLE: A Phase 1 Study of Multi-Tumor Associated Antigen Specific T Cells (MT-601) in Patients with Metastatic Pancreatic Cancer following frontline FOLFIRINOX
APPLICANT NAME: Vera, Juan F
ORGANIZATION: Marker Therapeutics, Inc.
PANEL NAME: 25.1 Product Development Panel-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**07/25/2024**	09/17/2024
	Method of submission	**CARS**	09/17/2024
	Within receipt period	**YES**	09/17/2024
	Request for extension to submit application after CARS closed	**N/A**	09/17/2024
	Request for extension for late application submission accepted	**N/A**	09/17/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	09/17/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/17/2024
	Assigned to primary reviewers	**08/01/2024**	09/17/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/18/2024
	Primary Reviewer 1 COI signed	**07/26/2024**	09/17/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/26/2024**	09/17/2024
	Primary Reviewer 3 COI signed	**07/26/2024**	09/17/2024
	Primary Reviewer 4 COI signed	**07/26/2024**	09/17/2024
	Primary Reviewer 5 COI signed	**07/26/2024**	09/17/2024
	Primary Reviewer 6 COI signed	**07/28/2024**	09/17/2024
	Primary Reviewer 7 COI signed	**07/26/2024**	09/17/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/28/2024**	09/17/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/03/2024**	09/17/2024
	Primary Reviewer 3 critique submitted	**08/26/2024**	09/17/2024
	Primary Reviewer 4 critique submitted	**08/26/2024**	09/17/2024
	Primary Reviewer 5 critique submitted	**08/24/2024**	09/17/2024
	Primary Reviewer 6 critique submitted	**08/26/2024**	09/17/2024
	Primary Reviewer 7 critique submitted	**08/18/2024**	09/17/2024
	COI indicated by non-primary reviewer	**NONE**	09/17/2024
	COI recused from participation	**N/A**	09/17/2024
	Peer Review Meeting	**09/09/2024**	09/17/2024
	Post review statements signed	**09/09/2024**	09/18/2024
	Third Party Observer Report	**09/10/2024**	09/18/2024
	Score report delivered to CPDO	**09/10/2024**	09/18/2024
	Recommended for due diligence and IP review	**YES**	09/17/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/09/2024**	11/04/2024
	Final intellectual property review submitted	**10/09/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	Due Diligence Meeting	**10/17/2024**	10/21/2024
	Third Party Observer Report	**10/17/2024**	10/22/2024
	Recommended for grant award	**YES**	10/21/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 DP250157
Texas Diagnostic and Devices Company Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 Diagnostic and Devices Company Awards* Request for Applications (RFA). CPRIT received 13 preliminary applications in response to this RFA.. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-8. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Pursuant to the approved communication waiver, Dr. Smith negotiated a reduced overall budget with the grant applicant. At the PIC meeting on November 6, Dr. Smith presented this application with the negotiated budget. The PIC unanimously recommended the application to the Oversight Committee with the lower overall budget.

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Texas Diagnostic and Devices Company Full Awards for Product Development Research
APPLICATION ID: DP250157
APPLICATION TITLE: Clinical Utility Study for the Commercial Launch of a Best-in-Class Liver Cancer Screening Blood Test for High-Risk Liver Disease Patients
APPLICANT NAME: Patnaik, Ritish
ORGANIZATION: Curve Biosciences
PANEL NAME: 25.1 Product Development Panel-8

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**07/25/2024**	09/18/2024
	Method of submission	**CARS**	09/18/2024
	Within receipt period	**YES**	09/18/2024
	Request for extension to submit application after CARS closed	**N/A**	09/18/2024
	Request for extension for late application submission accepted	**N/A**	09/18/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	09/18/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/18/2024
	Assigned to primary reviewers	**08/01/2024**	09/18/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/18/2024
	Primary Reviewer 1 COI signed	**07/26/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 3 COI signed	**07/28/2024**	09/18/2024
	Primary Reviewer 4 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 5 COI signed	**07/29/2024**	09/18/2024
	Primary Reviewer 6 COI signed	**07/30/2024**	09/18/2024
	Primary Reviewer 7 COI signed	**07/29/2024**	09/18/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/08/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/21/2024**	09/18/2024
	Primary Reviewer 3 critique submitted	**08/17/2024**	09/18/2024
	Primary Reviewer 4 critique submitted	**08/23/2024**	09/18/2024
	Primary Reviewer 5 critique submitted	**08/23/2024**	09/18/2024
	Primary Reviewer 6 critique submitted	**08/23/2024**	09/18/2024
	Primary Reviewer 7 critique submitted	**08/30/2024**	09/18/2024
	COI indicated by non-primary reviewer	**NONE**	09/18/2024
	COI recused from participation	**N/A**	09/18/2024
	Peer Review Meeting	**09/13/2024**	09/18/2024
	Post review statements signed	**09/13/2024**	09/18/2024
	Third Party Observer Report	**09/18/2024**	09/24/2024
	Score report delivered to CPDO	**09/13/2024**	09/18/2024
	Recommended for due diligence and IP review	**YES**	09/18/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/11/2024**	11/04/2024
	Final intellectual property review submitted	**10/07/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/18/2024
	COI recused from participation	**N/A**	10/18/2024
	Due Diligence Meeting	**10/15/2024**	10/18/2024
	Third Party Observer Report	**10/17/2024**	10/22/2024
	Recommended for grant award	**YES**	10/18/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 DP250159
Texas Therapeutics Company Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 Therapeutics Company Awards* Request for Applications (RFA). CPRIT received 21 preliminary applications in response to this RFA, including one withdrawn application. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 25.1 Product Development Panel-5. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the applications that did not move past the preliminary evaluation review stage in this cycle that is listed as "Final Scores for Preliminary Evaluations"

- A de-identified list of the final overall evaluation scores for applications submitted for full application review
- 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

On October 29, 2024, I notified Oversight Committee members that I granted the Chief Product Development Officer, Ken Smith, a waiver from the general prohibition against communicating with product development research cycle 25.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with each company that the Product Development Review Council recommended to the PIC. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Pursuant to the approved communication waiver, Dr. Smith negotiated a reduced overall budget with the grant applicant. At the PIC meeting on November 6, Dr. Smith presented this application with the negotiated budget. The PIC unanimously recommended the application to the Oversight Committee with the lower overall budget.

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/07/2024 02:54 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Product Development
MECHANISM: Texas Therapeutics Company Full Awards for Product Development Research
APPLICATION ID: DP250159
APPLICATION TITLE: (S)-TASIN-15 Phase 1 Dose Escalation, Optimization & RP2D Determination
APPLICANT NAME: Thapar, Neil C
ORGANIZATION: Barricade Therapeutics, Corp.
PANEL NAME: 25.1 Product Development Panel-5

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**04/12/2024**	09/17/2024
	RFA published in Texas.gov eGrants	**04/16/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) opened	**04/22/2024**	09/17/2024
	CPRIT Application Receipt System (CARS) closed	**07/25/2024**	09/17/2024
	Date application submitted	**07/25/2024**	09/18/2024
	Method of submission	**CARS**	09/18/2024
	Within receipt period	**YES**	09/18/2024
	Request for extension to submit application after CARS closed	**N/A**	09/18/2024
	Request for extension for late application submission accepted	**N/A**	09/18/2024
	Submission of application fee	**YES**	09/17/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	09/18/2024
	Donation(s) made to CPRIT / foundation	**NO**	09/18/2024
	Assigned to primary reviewers	**08/01/2024**	09/18/2024
	Applicant notified of review panel assignment	**08/01/2024**	09/18/2024
	Primary Reviewer 1 COI signed	**07/26/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 3 COI signed	**07/29/2024**	09/18/2024
	Primary Reviewer 4 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 5 COI signed	**07/29/2024**	09/18/2024
	Primary Reviewer 6 COI signed	**07/26/2024**	09/18/2024
	Primary Reviewer 7 COI signed	**07/29/2024**	09/18/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/17/2024**	09/18/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/21/2024**	09/18/2024
	Primary Reviewer 3 critique submitted	**08/23/2024**	09/18/2024
	Primary Reviewer 4 critique submitted	**08/22/2024**	09/18/2024
	Primary Reviewer 5 critique submitted	**08/13/2024**	09/18/2024
	Primary Reviewer 6 critique submitted	**08/26/2024**	09/18/2024
	Primary Reviewer 7 critique submitted	**08/10/2024**	09/18/2024
	COI indicated by non-primary reviewer	**NONE**	09/18/2024
	COI recused from participation	**N/A**	09/18/2024
	Peer Review Meeting	**09/11/2024**	09/18/2024
	Post review statements signed	**09/11/2024**	09/18/2024
	Third Party Observer Report	**09/16/2024**	09/18/2024
	Score report delivered to CPDO	**09/12/2024**	09/18/2024
	Recommended for due diligence and IP review	**YES**	09/18/2024
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**10/23/2024**	11/04/2024
	Intellectual Property conflict check	**09/11/2024**	11/04/2024
	Final intellectual property review submitted	**10/07/2024**	11/04/2024
	COI indicated by reviewer	**NONE**	10/18/2024
	COI recused from participation	**N/A**	10/18/2024
	Due Diligence Meeting	**10/15/2024**	10/18/2024
	Third Party Observer Report	**10/17/2024**	10/22/2024
	Recommended for grant award	**YES**	10/18/2024
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	10/29/2024
	COI recused from participation	**N/A**	10/29/2024
	Due Diligence Evaluation Meeting / PDRC Meeting	**N/A**	10/29/2024
	PDRC Meeting	**10/28/2024**	10/29/2024
	Third Party Observer Report	**10/30/2024**	11/07/2024
	Recommended for grant award	**YES**	10/29/2024
	PDRC Chair Notification to PIC and OC	**10/29/2024**	11/07/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 PP250004
Cancer Screening and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *Cancer Screening and Early Detection* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA, including three withdrawn applications. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In 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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:32 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Cancer Screening and Early Detection
APPLICATION ID: PP250004
APPLICATION TITLE: A Virtual, Centralized Lung Cancer Screening Program for Northeast Texas
APPLICANT NAME: Minnix, Jennifer A
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: 25.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**02/05/2024**	10/09/2024
	RFA Approved by CPO (revised)	**02/28/2024**	10/16/2024
	RFA published in Texas.gov eGrants	**02/09/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) opened	**03/07/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) closed	**06/06/2024**	10/09/2024
	Date application submitted	**06/03/2024**	10/10/2024
	Method of submission	**CARS**	10/10/2024
	Within receipt period	**YES**	10/10/2024
	Request for extension to submit application after CARS closed	**N/A**	10/10/2024
	Request for extension for late application submission accepted	**N/A**	10/10/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	10/10/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/10/2024
	Assigned to primary reviewers	**07/03/2024**	10/10/2024
	Applicant notified of review panel assignment	**06/27/2024**	10/09/2024
	Primary Reviewer 1 COI signed	**06/20/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 COI signed	**06/20/2024**	10/10/2024
	Primary Reviewer 3 COI signed	**07/01/2024**	10/10/2024
	Primary Reviewer 4 COI signed	**06/25/2024**	10/10/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/22/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/22/2024**	10/10/2024
	Primary Reviewer 3 critique submitted	**08/26/2024**	10/10/2024
	Primary Reviewer 4 critique submitted	**08/20/2024**	10/10/2024
	COI indicated by non-primary reviewer	**Martin Mahoney**	10/10/2024
	COI recused from participation	**YES**	10/10/2024
	Discussed at Peer Review Meeting	**YES**	10/10/2024
	Peer Review Meeting	**09/10/2024**	10/10/2024
	Peer Review Meeting end date	**09/11/2024**	10/10/2024
	Post review statements signed	**09/11/2024**	10/09/2024
	Third Party Observer Report	**09/16/2024**	09/27/2024
	Third Party Observer Report - Day 2	**09/16/2024**	09/27/2024
	Score report delivered to CPO	**09/12/2024**	10/09/2024
	Recommended for PRC review	**YES**	10/10/2024
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	PRC Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	11/06/2024
	Recommended for grant award	**YES**	10/21/2024
	PRC Chair Notification to PIC and OC	**10/21/2024**	10/21/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 PP250005
Cancer Screening and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *Cancer Screening and Early Detection* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA, including three withdrawn applications. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In 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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:32 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Cancer Screening and Early Detection
APPLICATION ID: PP250005
APPLICATION TITLE: Project 80% Colorectal Cancer Screening Program
APPLICANT NAME: Foxhall, Lewis E
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: 25.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**02/05/2024**	10/09/2024
	RFA Approved by CPO (revised)	**02/28/2024**	10/16/2024
	RFA published in Texas.gov eGrants	**02/09/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) opened	**03/07/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) closed	**06/06/2024**	10/09/2024
	Date application submitted	**06/04/2024**	10/10/2024
	Method of submission	**CARS**	10/10/2024
	Within receipt period	**YES**	10/10/2024
	Request for extension to submit application after CARS closed	**N/A**	10/10/2024
	Request for extension for late application submission accepted	**N/A**	10/10/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	10/10/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/10/2024
	Assigned to primary reviewers	**07/03/2024**	10/10/2024
	Applicant notified of review panel assignment	**06/27/2024**	10/09/2024
	Primary Reviewer 1 COI signed	**06/26/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 COI signed	**06/25/2024**	10/10/2024
	Primary Reviewer 3 COI signed	**06/26/2024**	10/10/2024
	Primary Reviewer 4 COI signed	**06/24/2024**	10/10/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/22/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/21/2024**	10/10/2024
	Primary Reviewer 3 critique submitted	**08/22/2024**	10/10/2024
	Primary Reviewer 4 critique submitted	**08/21/2024**	10/10/2024
	COI indicated by non-primary reviewer	**NONE**	10/10/2024
	COI recused from participation	**N/A**	10/10/2024
	Discussed at Peer Review Meeting	**YES**	10/10/2024
	Peer Review Meeting	**09/10/2024**	10/10/2024
	Peer Review Meeting end date	**09/11/2024**	10/10/2024
	Post review statements signed	**09/11/2024**	10/09/2024
	Third Party Observer Report	**09/16/2024**	09/27/2024
	Third Party Observer Report - Day 2	**09/16/2024**	09/27/2024
	Score report delivered to CPO	**09/12/2024**	10/09/2024
	Recommended for PRC review	**YES**	10/10/2024
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	PRC Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	11/06/2024
	Recommended for grant award	**YES**	10/21/2024
	PRC Chair Notification to PIC and OC	**10/21/2024**	10/21/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 PP250006
Cancer Screening and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *Cancer Screening and Early Detection* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA, including three withdrawn applications. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In 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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:32 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Cancer Screening and Early Detection
APPLICATION ID: PP250006
APPLICATION TITLE: Expansion of Cancer Screening and Early Detection Services to Rural & Medically Underserved Communities
APPLICANT NAME: Duckworth, Jessica
ORGANIZATION: The Rose
PANEL NAME: 25.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**02/05/2024**	10/09/2024
	RFA Approved by CPO (revised)	**02/28/2024**	10/16/2024
	RFA published in Texas.gov eGrants	**02/09/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) opened	**03/07/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) closed	**06/06/2024**	10/09/2024
	Date application submitted	**05/31/2024**	10/10/2024
	Method of submission	**CARS**	10/10/2024
	Within receipt period	**YES**	10/10/2024
	Request for extension to submit application after CARS closed	**N/A**	10/10/2024
	Request for extension for late application submission accepted	**N/A**	10/10/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**06/14/2024**	10/10/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/10/2024
	Assigned to primary reviewers	**07/03/2024**	10/10/2024
	Applicant notified of review panel assignment	**06/27/2024**	10/09/2024
	Primary Reviewer 1 COI signed	**06/25/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 COI signed	**06/19/2024**	10/10/2024
	Primary Reviewer 3 COI signed	**06/26/2024**	10/10/2024
	Primary Reviewer 4 COI signed	**06/19/2024**	10/10/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/21/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/11/2024**	10/10/2024
	Primary Reviewer 3 critique submitted	**08/22/2024**	10/10/2024
	Primary Reviewer 4 critique submitted	**08/23/2024**	10/10/2024
	COI indicated by non-primary reviewer	**NONE**	10/10/2024
	COI recused from participation	**N/A**	10/10/2024
	Discussed at Peer Review Meeting	**YES**	10/10/2024
	Peer Review Meeting	**09/10/2024**	10/10/2024
	Peer Review Meeting end date	**09/11/2024**	10/10/2024
	Post review statements signed	**09/11/2024**	10/09/2024
	Third Party Observer Report	**09/16/2024**	09/27/2024
	Third Party Observer Report - Day 2	**09/16/2024**	09/27/2024
	Score report delivered to CPO	**09/12/2024**	10/09/2024
	Recommended for PRC review	**YES**	10/10/2024
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	PRC Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	11/06/2024
	Recommended for grant award	**YES**	10/21/2024
	PRC Chair Notification to PIC and OC	**10/21/2024**	10/21/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 PP250009
Cancer Screening and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

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- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

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Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:32 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Cancer Screening and Early Detection
APPLICATION ID: PP250009
APPLICATION TITLE: The Central Texas Colorectal Cancer Screening Program (CTX-CCSP)
APPLICANT NAME: Shokar, Navkiran K
ORGANIZATION: The University of Texas at Austin
PANEL NAME: 25.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**02/05/2024**	10/09/2024
	RFA Approved by CPO (revised)	**02/28/2024**	10/16/2024
	RFA published in Texas.gov eGrants	**02/09/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) opened	**03/07/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) closed	**06/06/2024**	10/09/2024
	Date application submitted	**05/30/2024**	10/10/2024
	Method of submission	**CARS**	10/10/2024
	Within receipt period	**YES**	10/10/2024
	Request for extension to submit application after CARS closed	**N/A**	10/10/2024
	Request for extension for late application submission accepted	**N/A**	10/10/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	10/10/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/10/2024
	Assigned to primary reviewers	**07/03/2024**	10/10/2024
	Applicant notified of review panel assignment	**06/27/2024**	10/09/2024
	Primary Reviewer 1 COI signed	**06/19/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 COI signed	**06/25/2024**	10/10/2024
	Primary Reviewer 3 COI signed	**06/27/2024**	10/10/2024
	Primary Reviewer 4 COI signed	**06/19/2024**	10/10/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/22/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/20/2024**	10/10/2024
	Primary Reviewer 3 critique submitted	**08/05/2024**	10/10/2024
	Primary Reviewer 4 critique submitted	**08/26/2024**	10/10/2024
	COI indicated by non-primary reviewer	**NONE**	10/10/2024
	COI recused from participation	**N/A**	10/10/2024
	Discussed at Peer Review Meeting	**YES**	10/10/2024
	Peer Review Meeting	**09/10/2024**	10/10/2024
	Peer Review Meeting end date	**09/11/2024**	10/10/2024
	Post review statements signed	**09/11/2024**	10/09/2024
	Third Party Observer Report	**09/16/2024**	09/27/2024
	Third Party Observer Report - Day 2	**09/16/2024**	09/27/2024
	Score report delivered to CPO	**09/12/2024**	10/09/2024
	Recommended for PRC review	**YES**	10/10/2024
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	PRC Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	11/06/2024
	Recommended for grant award	**YES**	10/21/2024
	PRC Chair Notification to PIC and OC	**10/21/2024**	10/21/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 PP250016
Primary Prevention of Cancer

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *Primary Prevention of Cancer* Request for Applications (RFA). CPRIT received seven applications in response to this RFA, including one withdrawn application. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In 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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:32 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Primary Prevention of Cancer
APPLICATION ID: PP250016
APPLICATION TITLE: Screening and treatment for unhealthy alcohol use for cancer prevention in Central Texas – 2
APPLICANT NAME: Calderon-Mora, Jessica A
ORGANIZATION: The University of Texas at Austin
PANEL NAME: 25.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**02/05/2024**	10/09/2024
	RFA Approved by CPO (revised)	**02/28/2024**	10/16/2024
	RFA published in Texas.gov eGrants	**02/09/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) opened	**03/07/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) closed	**06/06/2024**	10/09/2024
	Date application submitted	**05/24/2024**	10/10/2024
	Method of submission	**CARS**	10/10/2024
	Within receipt period	**YES**	10/10/2024
	Request for extension to submit application after CARS closed	**N/A**	10/10/2024
	Request for extension for late application submission accepted	**N/A**	10/10/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**06/20/2024**	10/10/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/10/2024
	Assigned to primary reviewers	**07/03/2024**	10/10/2024
	Applicant notified of review panel assignment	**06/27/2024**	10/09/2024
	Primary Reviewer 1 COI signed	**06/19/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 COI signed	**06/20/2024**	10/10/2024
	Primary Reviewer 3 COI signed	**06/19/2024**	10/10/2024
	Primary Reviewer 4 COI signed	**06/19/2024**	10/10/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/23/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/22/2024**	10/10/2024
	Primary Reviewer 3 critique submitted	**08/26/2024**	10/10/2024
	Primary Reviewer 4 critique submitted	**08/24/2024**	10/10/2024
	COI indicated by non-primary reviewer	**NONE**	10/10/2024
	COI recused from participation	**N/A**	10/10/2024
	Discussed at Peer Review Meeting	**YES**	10/10/2024
	Peer Review Meeting	**09/10/2024**	10/10/2024
	Peer Review Meeting end date	**09/11/2024**	10/10/2024
	Post review statements signed	**09/11/2024**	10/09/2024
	Third Party Observer Report	**09/16/2024**	09/27/2024
	Third Party Observer Report - Day 2	**09/16/2024**	09/27/2024
	Score report delivered to CPO	**09/12/2024**	10/09/2024
	Recommended for PRC review	**YES**	10/10/2024
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	PRC Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	11/06/2024
	Recommended for grant award	**YES**	10/21/2024
	PRC Chair Notification to PIC and OC	**10/21/2024**	10/21/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 PP250018
Dissemination of CPRIT-Funded Cancer Control Interventions

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Dissemination of CPRIT-Funded Cancer Control Interventions* Request for Applications (RFA). CPRIT received one application in response to this RFA. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:33 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Dissemination of CPRIT-Funded Cancer Control Interventions
APPLICATION ID: PP250018
APPLICATION TITLE: Texas Comprehensive Access & Resources for Early Lung Cancer Prevention (TEX-CARE)
APPLICANT NAME: Zoorob, Roger
ORGANIZATION: Baylor College of Medicine
PANEL NAME: 25.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**02/05/2024**	10/09/2024
	RFA Approved by CPO (revised)	**02/28/2024**	10/16/2024
	RFA published in Texas.gov eGrants	**02/09/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) opened	**03/07/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) closed	**06/06/2024**	10/09/2024
	Date application submitted	**06/03/2024**	10/10/2024
	Method of submission	**CARS**	10/10/2024
	Within receipt period	**YES**	10/10/2024
	Request for extension to submit application after CARS closed	**N/A**	10/10/2024
	Request for extension for late application submission accepted	**N/A**	10/10/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	10/10/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/10/2024
	Assigned to primary reviewers	**07/03/2024**	10/10/2024
	Applicant notified of review panel assignment	**06/27/2024**	10/09/2024
	Primary Reviewer 1 COI signed	**06/24/2024**	10/10/2024
	Primary Reviewer 2 COI signed	**N/A**	10/10/2024
	Primary (Advocate) Reviewer 2 COI Signed	**06/20/2024**	10/10/2024
	Primary Reviewer 3 COI signed	**07/01/2024**	10/10/2024
	Primary Reviewer 4 COI signed	**06/20/2024**	10/10/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/19/2024**	10/10/2024
	Primary Reviewer 2 critique submitted	**N/A**	10/10/2024
	Primary (Advocate) Reviewer 2 Critique Submitted	**08/22/2024**	10/10/2024
	Primary Reviewer 3 critique submitted	**08/26/2024**	10/10/2024
	Primary Reviewer 4 critique submitted	**08/22/2024**	10/10/2024
	COI indicated by non-primary reviewer	**NONE**	10/10/2024
	COI recused from participation	**N/A**	10/10/2024
	Discussed at Peer Review Meeting	**YES**	10/10/2024
	Peer Review Meeting	**09/10/2024**	10/10/2024
	Peer Review Meeting end date	**09/11/2024**	10/10/2024
	Post review statements signed	**09/11/2024**	10/09/2024
	Third Party Observer Report	**09/16/2024**	09/27/2024
	Third Party Observer Report - Day 2	**09/16/2024**	09/27/2024
	Score report delivered to CPO	**09/12/2024**	10/09/2024
	Recommended for PRC review	**YES**	10/10/2024
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	PRC Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	11/06/2024
	Recommended for grant award	**YES**	10/21/2024
	PRC Chair Notification to PIC and OC	**10/21/2024**	10/21/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 PP250019
Cancer Screening and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *Cancer Screening and Early Detection* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA, including three withdrawn applications. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In 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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:33 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Cancer Screening and Early Detection
APPLICATION ID: PP250019
APPLICATION TITLE: Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas
APPLICANT NAME: Argenbright, Keith E
ORGANIZATION: The University of Texas Southwestern Medical Center
PANEL NAME: 25.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**02/05/2024**	10/09/2024
	RFA Approved by CPO (revised)	**02/28/2024**	10/16/2024
	RFA published in Texas.gov eGrants	**02/09/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) opened	**03/07/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) closed	**06/06/2024**	10/09/2024
	Date application submitted	**06/05/2024**	10/10/2024
	Method of submission	**CARS**	10/10/2024
	Within receipt period	**YES**	10/10/2024
	Request for extension to submit application after CARS closed	**N/A**	10/10/2024
	Request for extension for late application submission accepted	**N/A**	10/10/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**06/14/2024**	10/10/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/10/2024
	Assigned to primary reviewers	**07/03/2024**	10/10/2024
	Applicant notified of review panel assignment	**06/27/2024**	10/09/2024
	Primary Reviewer 1 COI signed	**06/20/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 COI signed	**06/20/2024**	10/10/2024
	Primary Reviewer 3 COI signed	**06/25/2024**	10/10/2024
	Primary Reviewer 4 COI signed	**07/01/2024**	10/10/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/22/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/22/2024**	10/10/2024
	Primary Reviewer 3 critique submitted	**08/21/2024**	10/10/2024
	Primary Reviewer 4 critique submitted	**08/26/2024**	10/10/2024
	COI indicated by non-primary reviewer	**NONE**	10/10/2024
	COI recused from participation	**N/A**	10/10/2024
	Discussed at Peer Review Meeting	**YES**	10/10/2024
	Peer Review Meeting	**09/10/2024**	10/10/2024
	Peer Review Meeting end date	**09/11/2024**	10/10/2024
	Post review statements signed	**09/11/2024**	10/09/2024
	Third Party Observer Report	**09/16/2024**	09/27/2024
	Third Party Observer Report - Day 2	**09/16/2024**	09/27/2024
	Score report delivered to CPO	**09/12/2024**	10/09/2024
	Recommended for PRC review	**YES**	10/10/2024
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	PRC Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	11/06/2024
	Recommended for grant award	**YES**	10/21/2024
	PRC Chair Notification to PIC and OC	**10/21/2024**	10/21/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 PP250046
Cancer Screening and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, 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 *Cancer Screening and Early Detection* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA, including three withdrawn applications. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In 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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:33 PM CT

FY: 2025
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Cancer Screening and Early Detection
APPLICATION ID: PP250046
APPLICATION TITLE: The Houston Prevenir, Ayudar, Poder (PAP) Project
APPLICANT NAME: Zamorano, Abigail S
ORGANIZATION: The University of Texas Health Science Center at Houston
PANEL NAME: 25.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**02/05/2024**	10/09/2024
	RFA Approved by CPO (revised)	**02/28/2024**	10/16/2024
	RFA published in Texas.gov eGrants	**02/09/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) opened	**03/07/2024**	10/09/2024
	CPRIT Application Receipt System (CARS) closed	**06/06/2024**	10/09/2024
	Date application submitted	**06/06/2024**	10/10/2024
	Method of submission	**CARS**	10/10/2024
	Within receipt period	**YES**	10/10/2024
	Request for extension to submit application after CARS closed	**N/A**	10/10/2024
	Request for extension for late application submission accepted	**N/A**	10/10/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**06/14/2024**	10/10/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/10/2024
	Assigned to primary reviewers	**07/03/2024**	10/10/2024
	Applicant notified of review panel assignment	**06/27/2024**	10/09/2024
	Primary Reviewer 1 COI signed	**06/25/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 COI signed	**06/19/2024**	10/10/2024
	Primary Reviewer 3 COI signed	**06/19/2024**	10/10/2024
	Primary Reviewer 4 COI signed	**06/19/2024**	10/10/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**08/22/2024**	10/10/2024
	Primary (Advocate) Reviewer 2 critique submitted	**08/21/2024**	10/10/2024
	Primary Reviewer 3 critique submitted	**08/20/2024**	10/10/2024
	Primary Reviewer 4 critique submitted	**08/26/2024**	10/10/2024
	COI indicated by non-primary reviewer	**NONE**	10/10/2024
	COI recused from participation	**N/A**	10/10/2024
	Discussed at Peer Review Meeting	**YES**	10/10/2024
	Peer Review Meeting	**09/10/2024**	10/10/2024
	Peer Review Meeting end date	**09/11/2024**	10/10/2024
	Post review statements signed	**09/11/2024**	10/09/2024
	Third Party Observer Report	**09/16/2024**	09/27/2024
	Third Party Observer Report - Day 2	**09/16/2024**	09/27/2024
	Score report delivered to CPO	**09/12/2024**	10/09/2024
	Recommended for PRC review	**YES**	10/10/2024
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	10/21/2024
	COI recused from participation	**N/A**	10/21/2024
	PRC Meeting	**10/18/2024**	10/21/2024
	Third Party Observer Report	**10/22/2024**	11/06/2024
	Recommended for grant award	**YES**	10/21/2024
	PRC Chair Notification to PIC and OC	**10/21/2024**	10/21/2024
PIC Review	**COI indicated by PIC member**	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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 RR250002
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Norihiro Goto

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 14 applications in response to this RFA during cycle 25.1. This application was assigned to the Scientific Review Council (SRC) for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC.

I 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE **Date and time exported: 11/06/2024 02:33 PM CT**

FY:	2025		
CYCLE:	1		
PROGRAM:	Recruitment		
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members		
APPLICATION ID:	RR250002		
APPLICATION TITLE	Dissecting Niche Cells in Cancer Immunity and Metastasis		
APPLICANT NAME:	Goto, Norihiro		
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center		
PANEL NAME:	Recruitment FY25_Cycle 1		
Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**06/17/2024**	10/04/2024
	RFA Approved by CSO (revised)	**08/01/2024**	10/04/2024
	RFA published in Texas.gov eGrants	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle opened	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle closed	**08/20/2024**	10/04/2024
	Date application submitted	**08/15/2024**	10/04/2024
	Method of submission	**CARS**	10/04/2024
	Within receipt period	**YES**	10/04/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**08/28/2024**	10/04/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/04/2024
	Assigned to primary reviewers	**08/30/2024**	10/04/2024
	Applicant notified of review panel assignment	**N/A**	10/04/2024
	Primary Reviewer 1 COI signed	**08/26/2024**	10/04/2024
	Primary Reviewer 2 COI signed	**08/28/2024**	10/04/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**09/07/2024**	10/04/2024
	Primary Reviewer 2 critique submitted	**09/07/2024**	10/04/2024
	COI indicated by non-primary reviewer	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	Discussed at Peer Review Meeting	**YES**	10/04/2024
	Peer Review Meeting	**09/12/2024**	10/04/2024
	Post review statements signed	**10/13/2024**	10/16/2024
	Third Party Observer Report	**09/16/2024**	10/04/2024
	Score report delivered to CSO	**09/16/2024**	10/04/2024
	Recommended for SRC review	**YES**	10/04/2024
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	SRC Meeting	**09/12/2024**	10/04/2024
	Third Party Observer Report	**09/16/2024**	10/04/2024
	Recommended for grant award	**YES**	10/04/2024
	SRC Chair Notification to PIC and OC	**10/16/2024**	10/17/2024
PIC Review	**Candidate not accepted asst. prof. tenure track position prior to SRC date**	**YES**	11/06/2024
	COI indicated by PIC member	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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	**NO**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	
Comments:			
Comment			Created Date
No Comment			

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR250014
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Xufeng Chen

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

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CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- 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 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:33 PM CT

FY:	2025
CYCLE:	1
PROGRAM:	Recruitment
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members
APPLICATION ID:	RR250014
APPLICATION TITLE	Decoding the Immune Network Dynamics in Acute Myeloid Leukemia
APPLICANT NAME:	Chen, Xufeng
ORGANIZATION:	The University of Texas M. D. Anderson Cancer Center
PANEL NAME:	Recruitment FY25_Cycle 1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**06/17/2024**	10/04/2024
	RFA Approved by CSO (revised)	**08/01/2024**	10/04/2024
	RFA published in Texas.gov eGrants	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle opened	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle closed	**08/20/2024**	10/04/2024
	Date application submitted	**08/15/2024**	10/04/2024
	Method of submission	**CARS**	10/04/2024
	Within receipt period	**YES**	10/04/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**08/28/2024**	10/04/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/04/2024
	Assigned to primary reviewers	**08/30/2024**	10/04/2024
	Applicant notified of review panel assignment	**N/A**	10/04/2024
	Primary Reviewer 1 COI signed	**08/28/2024**	10/04/2024
	Primary Reviewer 2 COI signed	**08/26/2024**	10/04/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**09/08/2024**	10/04/2024
	Primary Reviewer 2 critique submitted	**09/10/2024**	10/04/2024
	COI indicated by non-primary reviewer	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	Discussed at Peer Review Meeting	**YES**	10/04/2024
	Peer Review Meeting	**09/12/2024**	10/04/2024
	Post review statements signed	**10/13/2024**	10/16/2024
	Third Party Observer Report	**09/16/2024**	10/04/2024
	Score report delivered to CSO	**09/16/2024**	10/04/2024
	Recommended for SRC review	**YES**	10/04/2024
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	SRC Meeting	**09/12/2024**	10/04/2024
	Third Party Observer Report	**09/16/2024**	10/04/2024
	Recommended for grant award	**YES**	10/04/2024
	SRC Chair Notification to PIC and OC	**10/16/2024**	10/17/2024
PIC Review	**Candidate not accepted asst. prof. tenure track position prior to SRC date**	**YES**	11/06/2024
	COI indicated by PIC member	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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	**NO**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

Comments:

Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR250017
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Fangyu Liu

THE STATE OF TEXAS

COUNTY OF TRAVIS

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CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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- The 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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State of Texas
County of Travis

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SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE **Date and time exported: 11/06/2024 02:33 PM CT**

FY:	2025
CYCLE:	1
PROGRAM:	Recruitment
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members
APPLICATION ID:	RR250017
APPLICATION TITLE	Targeting Membrane Enzymes by Structure-Based Drug Discovery for Pancreatic Ductal Adenocarcinoma
APPLICANT NAME:	Liu, Fangyu
ORGANIZATION:	The University of Texas Southwestern Medical Center
PANEL NAME:	Recruitment FY25_Cycle 1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**06/17/2024**	10/04/2024
	RFA Approved by CSO (revised)	**08/01/2024**	10/04/2024
	RFA published in Texas.gov eGrants	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle opened	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle closed	**08/20/2024**	10/04/2024
	Date application submitted	**08/19/2024**	10/04/2024
	Method of submission	**CARS**	10/04/2024
	Within receipt period	**YES**	10/04/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	10/04/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/04/2024
	Assigned to primary reviewers	**08/30/2024**	10/04/2024
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	Primary Reviewer 2 COI signed	**08/26/2024**	10/04/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**09/10/2024**	10/04/2024
	Primary Reviewer 2 critique submitted	**09/08/2024**	10/04/2024
	COI indicated by non-primary reviewer	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	Discussed at Peer Review Meeting	**YES**	10/04/2024
	Peer Review Meeting	**09/12/2024**	10/04/2024
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	Score report delivered to CSO	**09/16/2024**	10/04/2024
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	COI recused from participation	**N/A**	10/04/2024
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	Third Party Observer Report	**09/16/2024**	10/04/2024
	Recommended for grant award	**YES**	10/04/2024
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PIC Review	**Candidate not accepted asst. prof. tenure track position prior to SRC date**	**YES**	11/06/2024
	COI indicated by PIC member	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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	**NO**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

Comments:

Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR250048
Recruitment of Rising Stars
Nomination of Dr. Daniel Addison

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Rising Stars* Request for Applications (RFA). CPRIT received five applications in response to this RFA during cycle 25.1. This application was assigned to the Scientific Review Council (SRC) for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC.

I 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE **Date and time exported: 11/06/2024 02:34 PM CT**

FY:	2025
CYCLE:	1
PROGRAM:	Recruitment
MECHANISM:	Recruitment of Rising Stars
APPLICATION ID:	RR250048
APPLICATION TITLE	Novel clinical biomarkers and mechanisms of Cardiotoxicity
APPLICANT NAME:	Addison, Daniel
ORGANIZATION:	The University of Texas Southwestern Medical Center
PANEL NAME:	Recruitment FY25_Cycle 1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**06/18/2024**	10/04/2024
	RFA Approved by CSO (revised)	**08/01/2024**	10/04/2024
	RFA published in Texas.gov eGrants	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle opened	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle closed	**08/20/2024**	10/04/2024
	Date application submitted	**08/20/2024**	10/04/2024
	Method of submission	**CARS**	10/04/2024
	Within receipt period	**YES**	10/04/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	10/04/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/04/2024
	Assigned to primary reviewers	**08/30/2024**	10/04/2024
	Applicant notified of review panel assignment	**N/A**	10/04/2024
	Primary Reviewer 1 COI signed	**08/26/2024**	10/04/2024
	Primary Reviewer 2 COI signed	**08/29/2024**	10/04/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**09/10/2024**	10/04/2024
	Primary Reviewer 2 critique submitted	**09/08/2024**	10/04/2024
	COI indicated by non-primary reviewer	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	Discussed at Peer Review Meeting	**YES**	10/04/2024
	Peer Review Meeting	**09/12/2024**	10/04/2024
	Post review statements signed	**10/13/2024**	10/16/2024
	Third Party Observer Report	**09/16/2024**	10/04/2024
	Score report delivered to CSO	**09/16/2024**	10/04/2024
	Recommended for SRC review	**YES**	10/04/2024
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	SRC Meeting	**09/12/2024**	10/04/2024
	Third Party Observer Report	**09/16/2024**	10/04/2024
	Recommended for grant award	**YES**	10/04/2024
	SRC Chair Notification to PIC and OC	**10/16/2024**	10/17/2024
PIC Review	**Candidate not accepted position prior to SRC date**	**YES**	11/06/2024
	COI indicated by PIC member	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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	**NO**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

Comments:

Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR250052
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Xiangdong Lv

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Kristen P. Doyle, who swore or affirmed to tell the truth, and stated as follows:

"My name is Kristen P. Doyle, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 14 applications in response to this RFA during cycle 25.1. This application was assigned to the Scientific Review Council (SRC) for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC.

I 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."

Kristen P. Doyle,
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 November, 2024, by KRISTEN P. DOYLE.

Sandra Reyes
Notary Public, State of Texas

SANDRA REYES
Notary Public, State of Texas
Comm. Expires October 21, 2025
Notary ID 12806624-2

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 11/06/2024 02:34 PM CT

FY:	2025
CYCLE:	1
PROGRAM:	Recruitment
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members
APPLICATION ID:	RR250052
APPLICATION TITLE	Harnessing Protein Translation Machinery to Overcome Resistance of KRAS Inhibitors
APPLICANT NAME:	Lv, Xiangdong
ORGANIZATION:	The University of Texas Health Science Center at Houston
PANEL NAME:	Recruitment FY25_Cycle 1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**06/17/2024**	10/04/2024
	RFA Approved by CSO (revised)	**08/01/2024**	10/04/2024
	RFA published in Texas.gov eGrants	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle opened	**06/21/2024**	10/04/2024
	CPRIT Application Receipt Cycle closed	**08/20/2024**	10/04/2024
	Date application submitted	**08/19/2024**	10/04/2024
	Method of submission	**CARS**	10/04/2024
	Within receipt period	**YES**	10/04/2024
Receipt, Referral, and Assignment	**Administrative review notification**	**08/28/2024**	10/04/2024
	Donation(s) made to CPRIT / foundation	**NO**	10/04/2024
	Assigned to primary reviewers	**08/30/2024**	10/04/2024
	Applicant notified of review panel assignment	**N/A**	10/04/2024
	Primary Reviewer 1 COI signed	**08/28/2024**	10/04/2024
	Primary Reviewer 2 COI signed	**08/26/2024**	10/04/2024
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**09/12/2024**	10/04/2024
	Primary Reviewer 2 critique submitted	**09/08/2024**	10/04/2024
	COI indicated by non-primary reviewer	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	Discussed at Peer Review Meeting	**YES**	10/04/2024
	Peer Review Meeting	**09/12/2024**	10/04/2024
	Post review statements signed	**10/13/2024**	10/16/2024
	Third Party Observer Report	**09/16/2024**	10/04/2024
	Score report delivered to CSO	**09/16/2024**	10/04/2024
	Recommended for SRC review	**YES**	10/04/2024
Final SRC Recommendation	**COI indicated by SRC member**	**NONE**	10/04/2024
	COI recused from participation	**N/A**	10/04/2024
	SRC Meeting	**09/12/2024**	10/04/2024
	Third Party Observer Report	**09/16/2024**	10/04/2024
	Recommended for grant award	**YES**	10/04/2024
	SRC Chair Notification to PIC and OC	**10/16/2024**	10/17/2024
PIC Review	**Candidate not accepted asst. prof. tenure track position prior to SRC date**	**YES**	11/06/2024
	COI indicated by PIC member	**None**	11/06/2024
	COI recused from participation	**N/A**	11/06/2024
	PIC Review Meeting	**11/06/2024**	11/06/2024
	Recommended for grant award	**YES**	11/06/2024
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	**NO**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

Comments:

Comment	Created Date
No Comment	

CPRIT retains the identity of the attesting party.