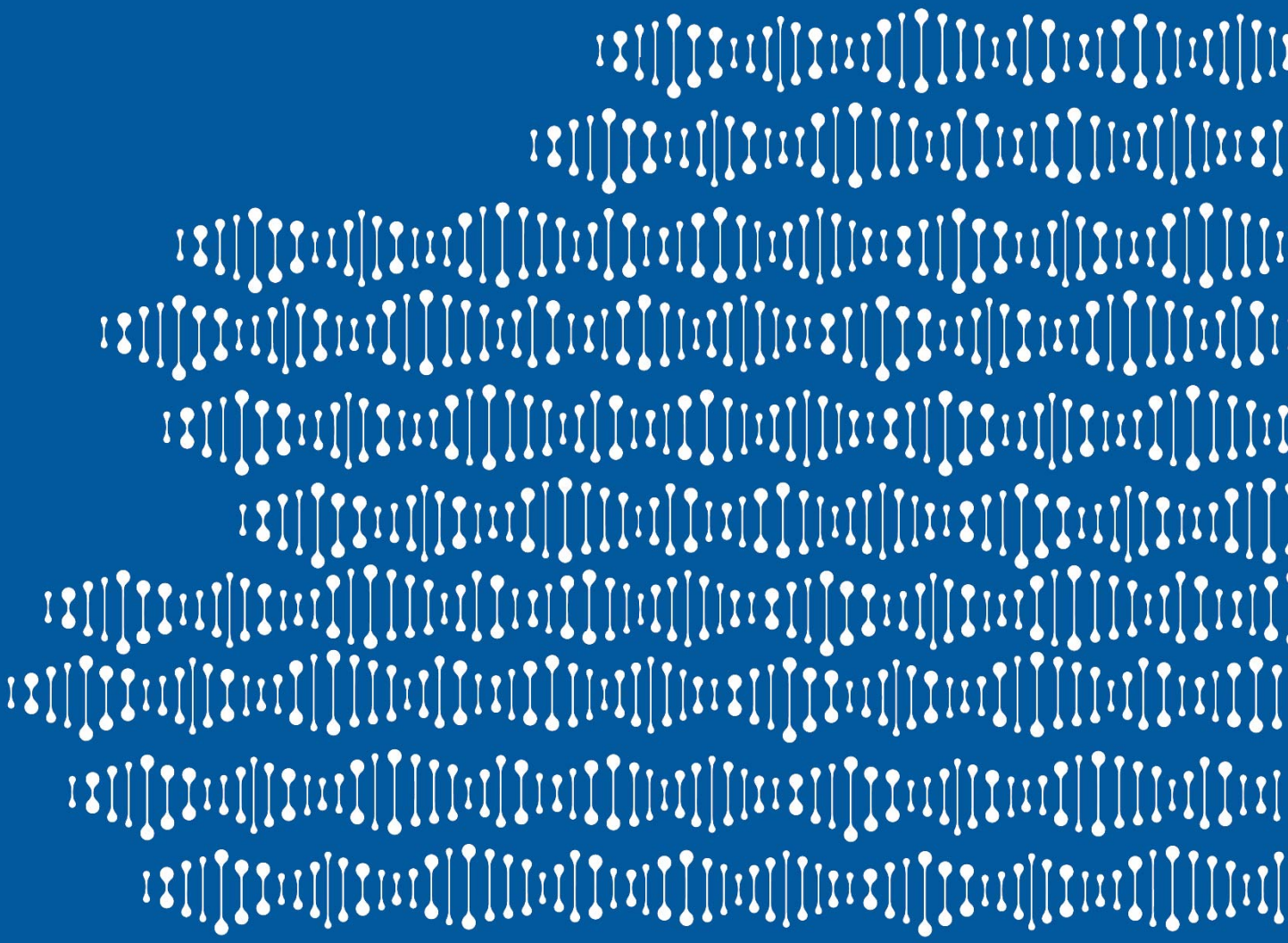
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# Proposed Grant Awards

May 17, 2023



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

**TO:** OVERSIGHT COMMITTEE MEMBERS

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

**SUBJECT:** ACADEMIC RESEARCH FY2023 RECRUITMENT AWARD RECOMMENDATIONS FY2023, CYCLE 23.4

**DATE:** MAY 17, 2023

The Scientific Review Council (SRC) and the Program Integration Committee recommendations for FY2023 recruitment cycle FY23, Cycle 23.4 includes three **awards** from two grant mechanisms totaling **$14,000,000** as displayed in Table 1. Please note that grant application RR230024 was withdrawn by the institution post the SRC recommendation.

**Table 1.**

| **Grant Mechanism** | **SRC Recommendations** | |
|---|---|---|
| | **Awards** | **Funding** |
| Recruitment of Established Investigators | 2 | $12,000,000 |
| Recruitment of First-Time, Tenure Track Faculty Members | 1 | $2,000,000 |
| **Total** | **3** | **$14,000,000** |

**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, childhood and adolescent cancers, and drug discovery. 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*** |
| 3 | Recruitment of outstanding cancer researchers to Texas | $14,000,000 |
| 2 | Childhood and Adolescent Cancers | $8,000,000 |
| *Some grant awards address more than one program priority and are double counted. | | |

## *1. RECRUITMENT OF ESTABLISHED INVESTIGATORS SLATE FY23.4*

**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 Established Investigators Awards:** The aim is to recruit outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.

**Funding levels for Recruitment of Established Investigators Awards:**
Up to $6 million over a period of 5 years.

**Recommended Awards:**
Four Recruitment of Established Investigators grant applications were submitted and two were recommended by the Scientific Review Council for an award.

**RR230032**
**Candidate:** Yuan Zhu, Ph.D.
**Funding Mechanism:** Recruitment of Established Investigator
**Applicant Organization:** The University of Texas Southwestern Medical Center
**Original Organization of Nominee:** Children's National Research Institute & Children's National Hospital
**Overall Evaluation Score** [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.8
**Recommended Total Budget Award and Duration:** $6,000,000
**CPRIT Priorities Addressed**: Recruitment of outstanding cancer researchers to Texas; Childhood and Adolescent Cancers

**Description:**
The University of Texas Southwestern Medical Center is nominating Yuan Zhu, PhD for a CPRIT Established Investigator Award, and appointment as Professor of Pediatrics in the Division of Hematology/Oncology and the Simmons Comprehensive Cancer Center. Dr. Zhu is a Professor at the George Washington University in Washington DC, where he also serves as the Gilbert Family Endowed Professor of Neurofibromatosis Research and Scientific Director of the Gilbert Family Neurofibromatosis Institute at Children's National Medical Center. Dr. Zhu is an international leader in elucidating the cellular and molecular mechanisms underlying nervous system tumor development and for moving his discoveries toward the clinic, particularly for cancers associated with Neurofibromatosis Type 1 (NF1), a relatively common cancer predisposition syndrome that causes significant morbidity and mortality in children and adults. Recently, his laboratory laid the scientific foundation for a funded, early-phase clinical trial

exploring a novel therapeutic approach for NF-1 associated malignant peripheral nerve sheath tumors, the leading cause of mortality in this population.

Dr. Zhu proposes to investigate three NF1-associated cancers with the goal of translating their preclinical findings into novel therapies. Each tumor represents a unique type of human cancer: (1) optic pathway glioma (NF1-OPG) – a benign tumor that affects visual function but has no potential for malignant transformation will be tackled using new genetically engineered mouse (GEM) NF1-OPG models to perform preclinical MEKi trials using non-invasive imaging and visual/functional assays to define developmental and treatment windows to preserve and improve visual function; (2) malignant peripheral nerve sheath tumor (NF1-MPNST) – a cancer with defined benign and premalignant lesions (plexiform and atypical neurofibroma, PNF and ANF, respectively) will be studied by performing parallel preclinical-clinical trials using a combination of MEKi and MDM2 inhibitors to develop preventive and treatment therapies for incurable NF1-MPNSTs; and (3) adult high-grade glioma and glioblastoma (GBM), a cancer with no benign precursor lesions will be approached by employing the new GEM models to target distant spread of Tp53/Nf1-mutant driven GBMs in vivo, which will provide new insights on treating GBMs in NF1 and Li-Fraumeni syndrome (TP53-mutant) patients.

Additionally, the high cancer incidence in NF1 syndromic patients provides an important entry point to investigate and develop preventive therapies for the more common sporadic cancers associated with acquired alterations in the NF1/RAS and TP53 pathways. Dr. Zhu will also have a significant impact beyond UT Southwestern. He has already formulated a scientific collaboration with a junior faculty member, Dr. Alejandro Lopez-Juarez at the University of Texas Rio Grande Valley, which will allow for mentorship and scientific collaboration focused on glial tumor biology in NF1.

**RR230029**
**Candidate:** Michael King, Ph.D.
**Funding Mechanism:** Recruitment of Established Investigator
**Applicant Organization:** Rice University
**Original Organization of Nominee:** Vanderbilt University
**Overall Evaluation Score** [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.0
**Recommended Total Budget Award and Duration:** $6,000,000
**CPRIT Priorities Addressed**: Recruitment of outstanding cancer researchers to Texas.

**Description:**
Rice University has nominated Michael King, PhD for a Recruitment of an Established Investigator award, and appointment as Professor in the prestigious Department of Bioengineering. Dr. King, a renowned chemical engineer and bioengineer, who works at the interface between cellular engineering, drug delivery, and nanotechnology, is currently the Lawrence Wilson Professor and Department Chair of Biomedical Engineering at Vanderbilt University.

Dr. King's research focuses on understanding key phenomena that occur within the bloodstream, including cancer metastasis and inflammation using engineering tools and concepts. His work

has shown that tumor cells often mimic physical mechanisms used by white blood cells to bind to blood vessel walls and extravasate into tissues. Understanding these processes has allowed him to design therapeutic targets to key receptors in this process to disrupt metastasis. For example, the selectin adhesion receptors important in leukocyte, stem cell, and circulating tumor cell trafficking have unique biophysics that make them ideal for targeted drug delivery. The King lab has pioneered the use of selectin proteins to deliver apoptotic death signals to tumor cells in flowing blood, and to deliver therapeutic cargo, e.g., siRNA, chemotherapeutics, encapsulated in nanoscale liposomes. He also has a strong interest in mechanotransduction, i.e., how circulating cells transduce fluid shear forces into changes in biochemical signaling cascades. His research team has shown that physiological levels of fluid shear stress modulate how tumor cells respond to apoptosis death signals in the bloodstream.

In Texas, Dr. King plans to leverage his expertise in cell mechanobiology, biotransport phenomena, and targeted drug delivery to develop new insights into the physical and molecular mechanisms of metastatic cancer, and translate these concepts to the clinic. He will focus on two major projects (1) Elucidating the mechanobiology of colorectal cancer cell aggregates at the blood interface, and their response to therapy; and (2) Developing a mechanobiology approach to CAR T-cell therapy applied to metastatic prostate cancer via achieving enhanced T cell activation and cytotoxic effect on tumor cells through ex vivo exposure to fluid shear stress stimulation of ion channels, leading to increased efficiency in infiltrating tumors.

## *2. RECRUITMENT OF FIRST-TIME TENURE TRACK FACULTY MEMBERS SLATE FY23.4*

**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:**
Three Recruitment of First-Time Tenure Track Faculty Members grant applications were submitted and two were recommended by the Scientific Review Council for an award. One application was withdrawn by the institution post the SRC recommendation.

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

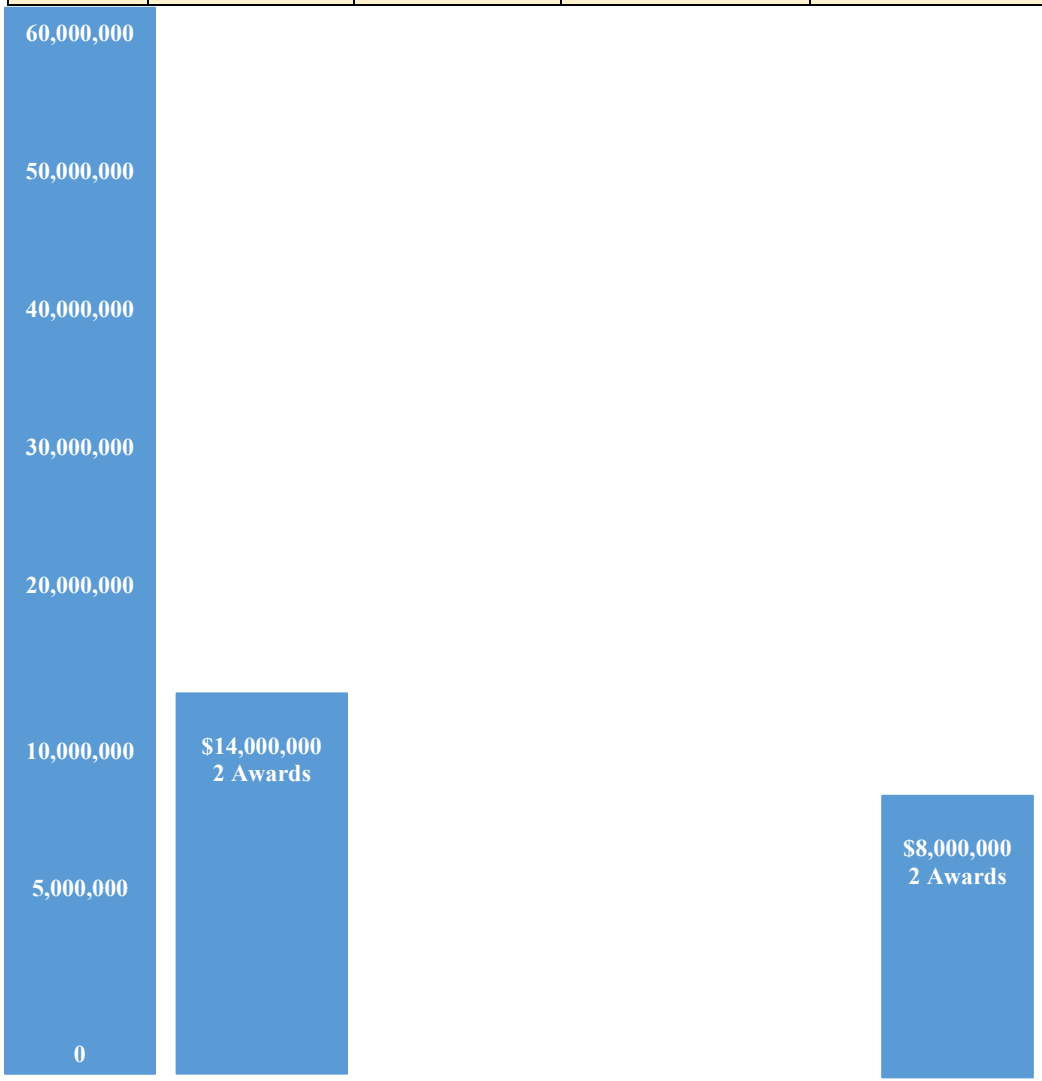
**RR230031**
**Candidate:** Dian Yang, Ph.D.
**Funding Mechanism:** Recruitment of First-Time, Tenure Track Faculty Member
**Applicant Organization:** The University of Texas Southwestern Medical Center
**Original Organization of Nominee:** Whitehead Institute for Biomedical Research
**Overall Evaluation 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; Childhood and Adolescent Cancers.

**Description:**
Dian Yang, PhD is being recruited as an Assistant Professor on the tenure track by the Children's Research Institute at the University of Texas Southwestern Medical Center, and is nominated for a CPRIT Scholar First-Time, Tenure-Track Faculty Member Award. Dr. Yang is an extraordinarily well-trained and accomplished junior scientist with expertise in bioinformatics, cancer genetics, and molecular biology. During his post-doctoral fellowship at the Whitehead Institute, Dr. Yang developed a new way of performing lineage tracing of cancer cells in a mouse model of lung cancer, using Cas9 to progressively introduce edits in synthetic target sites in a reporter gene expressed within the cancer cells. This strategy, which he recently reported in the premiere journal *Cell*, makes it possible to infer each cell's lineage history as well as its transcriptional state by single-cell RNA sequencing and, thus, to study cancer progression with unprecedented resolution, in vivo.

In his independent laboratory, he proposes to use this new lineage-tracing technique to study the mechanisms that regulate tumor evolution, cancer plasticity, and resistance to therapy. As a member of the Children's Research Institute, Dr. Yang will have the opportunity to collaborate and interact with a number of other CPRIT Scholars, and will be mentored by CPRIT Scholar, Dr. Sean Morrison, and CPRIT-funded pioneer in cancer metabolism – Dr. Ralph DeBerardinis.

**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 | Access to innovative clinical trials | Childhood and Adolescent Cancers | Population Disparities | Computational biology and analytic methods | Hepatocellular Cancer |





- **Recruitment of Established Investigators (RFA R-23-1 REI):**
  Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.
  Award: Up to $6 million over a period of five years.

- **Recruitment of First-Time Tenure Track Faculty Members (RFA R-23-1. 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.

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San Diego

ludwigcancerresearch.org

**Ludwig Institute for Cancer Research Ltd**

**Richard D. Kolodner Ph.D.**

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San Diego Branch

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April 14, 2023

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

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

Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on on March 16, 2023 (Cycle 23.4) to review and finalize applications submitted to CPRIT under the Recruitment of Established Investigator and Recruitment of First-Time, Tenure Track Faculty Members RFA mechanisms.

The SRC recommends four applications, which are inlcuded on the attached list. The recommended funding amounts and the overall evaluation scores are stated for the grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $16,000,000

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

Sincerely yours,

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

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| Rank | ID | Award Mechanism | Final Overall Score | Application Title | Candidate | Organization | Budget |
|---|---|---|---|---|---|---|---|
| 1 | RR230031 | RFTFM | 1.0 | Nomination of Dian Yang, Ph.D. for a CPRIT Recruitment of a First-Time Tenure-Track Faculty Member Award Investigator | Dian Yang | The University of Texas Southwestern Medical Center | $2,000,000 |
| 2 | RR230032 | REI | 1.8 | Nomination of Yuan Zhu, Ph.D. for a CPRIT Recruitment of an Established Investigator Award | Yuan Zhu | The University of Texas Southwestern Medical Center | $6,000,000 |
| 3 | RR230029 | REI | 2.0 | Recruitment of Established Investigators - Dr. King | Michael King | Rice University | $6,000,000 |
| 4 | RR230024 | RFTFM | 2.4 | First-Time, Tenure-Track: Dr. Esteban Orellana | Esteban Orellana | Baylor College of Medicine | $2,000,000 |

RFTFM- Recruitment of First-Time Tenure Track Faculty
REI- Recruitment of Established Investigators

Cancer Prevention & Research
Institute of Texas

# CEO Affidavit
# Supporting Information

**Academic Research Recruitment**
**FY 2023—Cycle 4**
***Recruitment of Established Investigators***

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-23.1-REI

## Recruitment of Established Investigators

**Please also refer to the Instructions for Applicants document, which will be posted on June 21, 2022**

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

**Application Receipt Dates:**

June 21, 2022-June 20, 2023

**FY 2023**

Fiscal Year Award Period

September 1, 2022-August 31, 2023

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# RFA VERSION HISTORY

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| 6/21/22 | RFA release |

# 1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

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

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

## 1.1. Academic Research Program Priorities

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

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure
- Achieving health equity and reducing cancer disparities

**Priorities Across CPRIT's 3 Programs:**

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

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

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects

- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions and population research addressing cancer disparities
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer
- Expanding access to innovative clinical trials

## 2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract world-class research scientists with distinguished professional careers to Texas universities and cancer research institutes to establish research programs that add research talent to the state. This award will support established academic leaders whose body of work has made an outstanding contribution to cancer 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. Candidates with research programs addressing CPRIT's priority areas for research are encouraged. These areas include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, population research addressing cancer disparities, 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. This award honors outstanding senior investigators with proven track records of research accomplishments combined with excellence in leadership

and teaching. All candidates should be recognized research or clinical investigators, held in the highest esteem by professional colleagues nationally and internationally, whose contributions have had a significant influence on their discipline and, likely, beyond. They must have clearly established themselves as exemplary faculty members with exceptional accomplishments in teaching and advising and/or basic, translational, population-based, or clinical cancer research activities. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Candidates will be leaders capable of initiating and developing creative ideas leading to novel solutions related to cancer prevention and control, detection, diagnosis, and/or treatment. They are also expected to maintain and lead a strong research group and have a stellar, high-impact publication portfolio, as well as continue to secure external funding. Furthermore, recipients will lead and inspire undergraduate and graduate students interested in pursuing research careers and will engage in collegial and collaborative relationships with others within and beyond their traditional discipline in an effort to expand the boundaries of cancer research.

Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates should be at the career level of a full professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience as 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 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 an Established Investigator must be complemented by a strong financial institutional commitment to the recruitment. The institutional commitment should be clearly documented in the application (see section 8.2.2) and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate 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. Grant support will be awarded based upon the breadth and nature of the research program proposed. Grant funds of up to $6,000,000 (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 $6,000,000 for the term of the award are acceptable if warranted by the scope of the research. Exceptions exceeding this limit will be entertained only if there is compelling written justification. 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 candidate but may not be used to construct or renovate laboratory space.**

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 2023 is limited to a maximum of $200,000. In other words, an individual may request salary proportional to the percent of effort up to a maximum of $200,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

**Note:** Depending on the availability of funds, review cycles may be reduced, and/or the number of applications per institution may be capped, and 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, 2023) or in the first quarter of the next fiscal year (starting September 1, 2023).

## 6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.

- A candidate may be nominated by only 1 institution. If more than 1 institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.
- An institution is allowed to submit **only 6** Recruitment applications (either a Recruitment of Established Investigator, or a Recruitment of First-Time, Tenure-Track Faculty Member) **during the FY23 application receipt period.** An exception will be made for **up to 3** additional submissions of a Recruitment of Established Investigator application, if the application involves a meaningful collaboration with a Texas Regional Excellence in Cancer eligible institution (see eligible Universities in IFA). Applications that exceed these limits will be returned. Institutions may use their own discretion as to the timing of submission of applications in FY23, with the understanding that the limit of 6 applications per FY23 receipt period will be strictly upheld (with the exception noted above).
- A candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating institution of the Scientific Review Council's review decision following the Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, **and reside in Texas for the duration of the appointment**. The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of professor (or equivalent) at an accredited academic institution, research institution,

industry, government agency, or private foundation. The candidate must not reside in Texas at the time the application is submitted.

- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

## 7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Established Investigators award mechanism. Any nomination for the Recruitment of Established Investigators that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be

resubmitted. A nomination for the Recruitment of Established Investigators that was previously submitted to CPRIT for any of the recruitment RFA mechanisms and reviewed and recommended for funding but declined by the candidate may be submitted in response to this RFA if the candidate 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] document 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. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (Nominator) must create a user account in the system (which includes the Nominator's credentials and email address) to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

**Dependent upon available funding, applications will be accepted within a 6-review-cycle schedule throughout FY23, as displayed in the table below.**

| Review Cycle | Open date | Close date |
|---|---|---|
| 23.1 | 6/21/2022 | 8/20/2022 |
| 23.2 | 8/23/2022 | 10/20/2022 |
| 23.3 | 10/21/2022 | 12/20/2022 |
| 23.4 | 12/21/2022 | 2/20/2023 |
| 23.5 | 2/21/2023 | 4/20/2023 |
| 23.6 | 4/21/2023 | 6/20/2023 |

In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the closing day of each cycle (see table above for closing date of each cycle) will be reviewed by the 15th day of the following month. For an application to be considered for review during the cycle, that application must be submitted on or before 11:59 PM central time. 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. **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 *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 (2,500 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

### 8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of an Established Investigator Faculty should be complemented by a strongly documented institutional commitment to the recruitment. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

***The following guidelines should be followed when documenting the institutional commitment to the candidate:***

- The institutional commitment should be clearly documented in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and include the

amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

- The institutional commitment letter must include the following statement regarding the institution's financial commitment required to meet the 50% match.
    - This institutional financial commitment will not be offset by funds from an investigator-initiated award received by the candidate. If an award dictates that such funds must be used for salary, the corresponding amount of institutional funds committed to pay the candidate's salary will be redirected to allow the candidate to use them for program support.
- Institutional commitment as described above must be presented in a table (example below), that clearly identifies the salary amount, sources of salary, and any additional research support from institutional sources over the course of the CPRIT award. Sources of support for the candidate's full salary, including summer salary, for the duration of the award must be documented. If the candidate 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 candidate.
- Include a brief job description for the candidate should recruitment be successful.
- Describe the institutional environment and any professional commitments to the candidate including, but not limited to, dedicated personnel, access to students, space assignment, and access to shared equipment, and discuss all other agreements between the institution and the candidate.
- Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment, through development of strategic collaborations, will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.

- Note that Texas law allows an institution of higher learning to use its federal indirect cost rate credit to comply with the requirement to demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award (see section 12). However, a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the candidate.

***Example of an acceptable Institutional Commitment table:***

| **Candidate's Name, Institutional Commitments** | | | | | |
|---|---|---|---|---|---|
| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| Salary/Benefits | | | | | |
| Research Support | | | | | |
| Administrative Support | | | | | |
| Moving Expenses | | | | | |

Total =

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

### 8.2.3. Letter of Support from Department Chair (up to 2 pages)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

**Recruitment Activities:** 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 candidate. 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—including impact on diversity, equity, and inclusion, if applicable—and the expected impact of the recruitment on the institution (or department) and the burden of cancer in Texas (if applicable).

**Caliber of Candidate:** The letter should include a description of the caliber of the candidate and justification of nomination of the candidate by the institution. CPRIT recognizes that there is variability in the metrics of impact applicable across the continuum of cancer research. For

example, is 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 Candidate Duties and Certification of 70% Time Commitment to Research:** While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

### 8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

### 8.2.5. Summary of Goals and Objectives (2,000 characters)

List goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

### 8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section should be listed in the Publications/References section (see 8.2.7).**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.**

"I understand that I do not need to have made a commitment to <*nominating institution*> before this application has been submitted. However, I also understand that only 1 Texas institution may

nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are not allowed after the application is submitted to CPRIT."

### 8.2.7. Publications/References (1 Page)

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

### 8.2.8. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2-page synergy plan (see IFA).

### 8.2.9. Publications

Provide the 5 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

### 8.2.10. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

### 8.2.11. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be

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

### 8.2.12. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

### 8.2.13. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award. **This section of the application must be prepared by the candidate.** If the application is approved for funding, this section will be made publicly available on CPRIT's website. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

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

## 9. APPLICATION REVIEW

### 9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a cycle of 6 review periods per year by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee.

The review process is described more fully in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

### 9.1.1. Confidentiality of Review

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

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

**By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.**

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

## 9.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. **Also, of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution.** It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have a reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

**Quality of the Candidate:** Has the candidate made significant, transformative, and sustained contributions to basic, translational, clinical, or population-based cancer research? Is the candidate an established and nationally and/or internationally recognized leader in the field? Has the candidate demonstrated excellence in leadership and teaching? Has the candidate provided mentorship, inspiration, and/or professional training opportunities to junior scientists and students? Does the candidate have a strong record of research funding? Does the candidate have a publication history in high-impact journals within cancer research broadly, or within their specialty field, if applicable? Does the candidate show evidence of collaborative interaction with others?

**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 expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques? Does the research program integrate with and/or increase collaborative research efforts and relationships at the nominating institution?

**Relevance of Candidate's Research:** Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term, 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 candidate's research program? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program?

## 10. KEY DATES

**RFA**

RFA Release June 21, 2022

**Application Receipt and Review Timeline**

| Cycle | Application Receipt Date | Application Closing Date | Anticipated Application Review |
|---|---|---|---|
| 23.1 | 6/21/2022 | 8/20/2022 | 9/15/2022 |
| 23.2 | 8/23/2022 | 10/20/2022 | 11/10/2022 |
| 23.3 | 10/21/2022 | 12/20/2022 | 1/12/2023 |
| 23.4 | 12/21/2022 | 2/20/2023 | 3/16/2023 |
| 23.5 | 2/21/2023 | 4/20/2023 | 5/11/2023 |
| 23.6 | 4/21/2023 | 6/20/2023 | 7/13/2023 |

## 11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract

provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. CPRIT requires funding acknowledgement to include the award grant ID on all print and visual materials that are funded in whole or in part by CPRIT grants. Examples of print and visual materials include, but are not limited to, publications, brochures, pamphlets, project websites, videos, and media materials. Grantees must have written approval from CPRIT prior to the purchase of any equipment. If the equipment is clearly defined in the grantee's budget submitted with the initiating award requirements, then approval of the grant award constitutes "prior approval" for the purchase. Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

**Continuation of funding is contingent upon the timely receipt of these reports**. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

# 12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703, for specific requirements regarding the demonstration of available funding.

# 13. CONTACT INFORMATION

## 13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff members are not in a position to answer questions regarding scientific aspects of applications.

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

## 13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Director of Academic Research.

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

# Third Party Observer Report

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.4 Academic Research Recruitment Review Panel
# (23.4_SRC_REC)
# Observation Report

| | |
|---|---|
| Report No. | 2023-03-16 23.4_SRC_REC |
| Program Name: | Academic Research |
| Panel Name: | 23.4 Academic Research Recruitment Review Panel (23.4 _SRC_REC) |
| Panel Date: | March 16, 2023 |
| Report Date: | March 20, 2023 |

## *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 23.4 Academic Research Recruitment Review Panel (23.4_SRC_REC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on March 16, 2023.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed
- Panelists: One (1) panel chair, and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) Conflicts of Interest (COIs) identified prior to and/or during the meeting. Conflicts of Interest were excluded from discussions concerning applications for which there was a conflict.

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

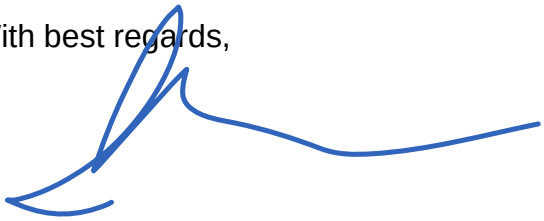
## *CONCLUSION*

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

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

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

With best regards,



Mara Ash, CIA, CGAP, CGFM, 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 23.4

Awards Announced at the May 17, 2023, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 23.4 include: *Recruitment of Established Investigators* and *Recruitment of First-Time, Tenure-Track Faculty Members.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

| Application ID | Principal Investigator | Organization | Conflict Noted by Reviewer |
|---|---|---|---|
| **Applications considered by the PIC and Oversight Committee:** | | | |
| RR230032 | W. P. Andrew Lee | The University of Texas Southwestern Medical Center | E. Fearon |
| **Applications not considered by the PIC or Oversight Committee:** | | | |
| RR230028 | Luay Nakhleh | Rice University | M. Pomper |

# De-Identified Overall Evaluation Scores

# Recruitment of Established Investigators

Academic Research Recruitment Cycle 23.4

| Application ID | Final Overall Evaluation Score |
|---|---|
| RR230032* | 1.8 |
| RR230029* | 2.0 |
| bb | 2.8 |
| bc | 3.8 |

* Recommended for funding.

# Final Overall Evaluation Scores and Rank Order Scores

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

**Ludwig Institute for Cancer Research Ltd**

**Richard D. Kolodner Ph.D.**

Head, Laboratory of Cancer Genetics
San Diego Branch

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

**rkolodner@health.ucsd.edu**

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

**T** 858 534 7804
**F** 858 534 7750

April 14, 2023

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

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

Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on on March 16, 2023 (Cycle 23.4) to review and finalize applications submitted to CPRIT under the Recruitment of Established Investigator and Recruitment of First-Time, Tenure Track Faculty Members RFA mechanisms.

The SRC recommends four applications, which are inlcuded on the attached list. The recommended funding amounts and the overall evaluation scores are stated for the grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $16,000,000

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

Sincerely yours,

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

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

| Rank | ID | Award Mechanism | Final Overall Score | Application Title | Candidate | Organization | Budget |
|---|---|---|---|---|---|---|---|
| 1 | RR230031 | RFTFM | 1.0 | Nomination of Dian Yang, Ph.D. for a CPRIT Recruitment of a First-Time Tenure-Track Faculty Member Award Investigator | Dian Yang | The University of Texas Southwestern Medical Center | $2,000,000 |
| 2 | RR230032 | REI | 1.8 | Nomination of Yuan Zhu, Ph.D. for a CPRIT Recruitment of an Established Investigator Award | Yuan Zhu | The University of Texas Southwestern Medical Center | $6,000,000 |
| 3 | RR230029 | REI | 2.0 | Recruitment of Established Investigators - Dr. King | Michael King | Rice University | $6,000,000 |
| 4 | RR230024 | RFTFM | 2.4 | First-Time, Tenure-Track: Dr. Esteban Orellana | Esteban Orellana | Baylor College of Medicine | $2,000,000 |

RFTFM- Recruitment of First-Time Tenure Track Faculty
REI- Recruitment of Established Investigators

Cancer Prevention & Research
Institute of Texas

# CEO Affidavit
# Supporting Information

**Academic Research Recruitment**
**FY 2023—Cycle 4**
***Recruitment of First-Time, Tenure-Track Faculty Members***

# Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS

# RFA R-23.1-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, 2022**

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

**Application Receipt Dates:**

June 21, 2022-June 20, 2023

**FY 2023**

Fiscal Year Award Period

September 1, 2022-August 31, 2023

# TABLE OF CONTENTS

## RFA VERSION HISTORY

| | |
|---|---|
| 6/21/22 | RFA release |

# 1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

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

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

## 1.1. Academic Research Program Priorities

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

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure
- Achieving health equity and reducing cancer disparities

**Priorities Across CPRIT's 3 Programs:**

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

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

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects

- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions and population research addressing cancer disparities
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer
- Expanding access to innovative clinical trials

## 2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract very promising investigators who are pursuing their first faculty appointment at the level of assistant professor (**first-time, tenure-track faculty members**). These individuals must have demonstrated academic excellence, innovation during predoctoral and/or postdoctoral research training, commitment to pursuing cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research 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. Candidates with research programs addressing CPRIT's priority areas for research are encouraged. These include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational oncology and analytic methods, population 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 candidates are expected to have completed their

doctoral and fellowship training and to have clearly demonstrated truly superior ability as evidenced by their accomplishments during training, proposed research plan, publication record, and letters of recommendation. This CPRIT-supported initiative is designed to enhance innovative programs of excellence by providing research support for promising, early-stage investigators **seeking their first tenure-track position.**

CPRIT will provide start-up funding for newly independent investigators, with the goal of augmenting and expanding the institution's efforts in cancer research. Candidates will be expected to develop research projects within the sponsoring institution. Projects should be appropriate for a newly independent investigator and should foster the development of preliminary data that can be used to prepare applications for future independent research project grants to further both the investigator's research career and the CPRIT mission. The institution will be expected to work with each newly recruited research faculty member to design and execute a faculty career development plan consistent with his or her research emphasis. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

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

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 must therefore be complemented by a strong institutional commitment to the candidate's career development that includes financial commitments that are in addition to the CPRIT award. The institutional commitment should be clearly documented in the application (see section 8.2.2) and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate for his or her research program by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

## 5. FUNDING INFORMATION

This award is up to 5 years and is not renewable, although individuals may apply for other future CPRIT funding as appropriate. Grant funds of up to $2,000,000 (total costs) for the 5-year period may be requested. 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 candidate to support his or her research program. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years except under extraordinary circumstances with strong justification for a no-cost extension. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified and a detailed justification is provided along with an institutional plan should the additional funds not be approved. Scholars may request funds for travel for 2 project staff to attend CPRIT's conference.

**Funds from this CPRIT award may not be used for salary support of this candidate or to construct or renovate laboratory space.**

**Note:** Depending on the availability of funds, nominations submitted in response to this Request for Applications (RFA) during the current receipt period may be announced and awarded either

in the current fiscal year (prior to August 31, 2023) or in the first quarter of the next fiscal year (starting September 1, 2023).

## 6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.
- An institution is allowed to submit **only 6** Recruitment applications (either a Recruitment of Established Investigator, or a Recruitment of First-Time, Tenure-Track Faculty Member) **during the FY23 application receipt period.** An exception will be made for **up to 3** additional submissions of a Recruitment of Established Investigator application, if the application involves a meaningful collaboration with a Texas Regional Excellence in Cancer eligible institution (see eligible Universities in IFA). Applications that exceed these limits will be returned. Institutions may use their own discretion as to the timing of submission of applications in FY23, with the understanding that the limit of 6 applications per FY23 receipt period will be strictly upheld (with the exception noted above).
- A candidate who has already accepted a position as assistant professor tenure track at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating

institution of the Scientific Review Council's review decision following the Scientific Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.

- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, **and reside in Texas for the duration of the appointment.** The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate must ***not*** hold an appointment at the rank of assistant professor or above (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation. Candidates holding non-tenure-track appointments at the rank of assistant professor are ***not*** eligible for this award. Examples of such appointments include research assistant professor, adjunct research assistant professor, assistant professor (non-tenure track).
- The candidate may or may not reside in Texas at the time the application is submitted and may be nominated for a faculty position at the Texas institution where he or she is completing postdoctoral training or at another Texas institution.
- Applications nominating a candidate for a faculty position at the Texas institution where he or she is completing postdoctoral training that do not clearly demonstrate a subsequent career pathway to independence for the candidate will not be looked upon with favor.
- Successful candidates will be offered tenure-track academic positions at the rank of assistant professor.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or

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

- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

# 7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of First-Time, Tenure-Track Faculty Members award mechanism. Any nomination for the Recruitment of First-Time, Tenure-Track Faculty Members that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

# 8. RESPONDING TO THIS RFA

## 8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean.

The individual submitting the application (Nominator) must create a user account in the system (which includes the Nominator's credentials and email address) to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

**Dependent upon available funding, applications will be accepted within a 6-review-cycle schedule throughout FY23, as displayed in the table below.**

| Review Cycle | Open date | Close date |
|---|---|---|
| 23.1 | 6/21/2022 | 8/20/2022 |
| 23.2 | 8/23/2022 | 10/20/2022 |
| 23.3 | 10/21/2022 | 12/20/2022 |
| 23.4 | 12/21/2022 | 2/20/2023 |
| 23.5 | 2/21/2023 | 4/20/2023 |
| 23.6 | 4/21/2023 | 6/20/2023 |

In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the closing day of each cycle (see table above for closing date of each cycle) will be reviewed by the 15th day of the following month. For an application to be considered for review during the cycle, that application must be submitted on or before 11:59 PM central time. 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. **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 candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

### 8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a first-time, tenure-track faculty must therefore be complemented by a strongly documented institutional commitment to the candidate's career development that includes financial commitments that are in addition to the CPRIT award.

***The following guidelines should be followed when documenting the institutional commitment to the candidate:***

- The institutional commitment should be clearly documented in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.
- The institutional commitment letter must include the following statement regarding the institution's financial commitment required to meet the 50% match.
    - This institutional financial commitment will not be offset by funds from a career transition award (K99/R00) or an investigator-initiated award received by the candidate. If an award dictates that such funds must be used for salary, the corresponding amount of institutional funds committed to pay the candidate's salary will be redirected to allow the candidate to use them for program support.
- Institutional commitment as described above must be presented in a table (example below) that clearly identifies the salary amount, sources of salary, and any additional research support from institutional sources over the course of the CPRIT award. Sources

of support for the candidate's full salary, including summer salary, for the duration of the award must be documented. If the candidate 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 candidate.

- Include a brief job description for the candidate should recruitment be successful.
- Describe the institutional environment and any professional commitments to the candidate including, but not limited to, dedicated personnel, access to students, space assignment, and access to shared equipment, and discuss all other agreements between the institution and the candidate.
- Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.
- Note that Texas law allows an institution of higher learning to use its federal indirect cost rate credit to comply with the requirement to demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award (see section 12). However, a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the candidate.

***Example of an acceptable Institutional Commitment table:***

| **Candidate's Name, Institutional Commitments** | | | | | |
|---|---|---|---|---|---|
| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| Salary/Benefits | | | | | |
| Research Support | | | | | |
| Administrative Support | | | | | |
| Moving Expenses | | | | | |

Total =

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

### 8.2.3. Letter of Support from Department Chair (up to 2 pages)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

**Recruitment Activities:** The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate. 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 candidate. 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—including impact on diversity, equity, and inclusion, if applicable—and the expected impact of the recruitment on the institution (or department) and the burden of cancer in Texas (if applicable).

**Caliber of Candidate:** The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution. CPRIT recognizes that there is variability in the metrics of impact applicable across the continuum of cancer research. For example, is 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 Candidate Duties and Certification of 70% Time Commitment to Research:** While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

The letter of support from the department chair must also do the following:

1. Describe how the candidate will be independent and autonomous in developing his or her research program at the institution.
2. Present a plan for mentoring that includes the design and execution of a faculty career development plan for the candidate.

### 8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate. Only articles that have been published or that have been accepted for publication ("in press") should be cited.

### 8.2.5. Summary of Goals and Objectives (2,000 characters)

List goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

### 8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section should be included in the Publications/References section (see 8.2.7).**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.**

"I understand that I do not need to have made a commitment to <*nominating institution*> before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are not allowed after the application is submitted to CPRIT."

### 8.2.7. Publications/References (1 page)

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

### 8.2.8. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2-page synergy plan (see IFA).

### 8.2.9. Publications

Provide the 3 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

### 8.2.10. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

### 8.2.11. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

### 8.2.12. Letters of Recommendation

Provide 3 letters of recommendation from individuals who are in a position to detail the candidate's academic and scientific research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research.

### 8.2.13. Research Environment (1 page)

Clearly and concisely describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

### 8.2.14. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award. **This section of the application must be prepared by the candidate.** If the application is approved for funding, this section will be made publicly available on CPRIT's website. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

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

## 9. APPLICATION REVIEW

### 9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a cycle of 6 review periods per year by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to

the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

### 9.1.1. Confidentiality of Review

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

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

**By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.**

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

this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

## 9.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. **Also, of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution.** It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have a reasonable expectation that the recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his or her proposed research program, and his or her long-term 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 Candidate:** Has the candidate demonstrated academic excellence? Has the candidate received excellent predoctoral and postdoctoral training? Does the candidate show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated a commitment to cancer research? Has the candidate demonstrated independence or the potential for independence?

**Scientific Merit of Proposed Research:** Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will the proposed research generate preliminary data that can be used for the preparation of applications for future independent research project grants?

**Relevance of Candidate's Research:** Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term 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 candidate's academic and clinical research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research?

**Research Environment:** Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on growing his or her research? Has the institution identified a mentor who will design and execute a faculty career development plan for the candidate?

## 10. KEY DATES

**RFA**

RFA Release June 21, 2022

**Application Receipt and Review Timeline**

| Cycle | Application Receipt Date | Application Closing Date | Anticipated Application Review |
|---|---|---|---|
| 23.1 | 6/21/2022 | 8/20/2022 | 9/15/2022 |
| 23.2 | 8/23/2022 | 10/20/2022 | 11/10/2022 |
| 23.3 | 10/21/2022 | 12/20/2022 | 1/12/2023 |
| 23.4 | 12/21/2022 | 2/20/2023 | 3/16/2023 |
| 23.5 | 2/21/2023 | 4/20/2023 | 5/11/2023 |
| 23.6 | 4/21/2023 | 6/20/2023 | 7/13/2023 |

## 11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. CPRIT requires funding acknowledgement to include the award grant ID on all print and visual materials that are funded in whole or in part by CPRIT grants. Examples of print and visual materials include, but are not limited to, publications, brochures, pamphlets, project websites, videos and media materials. Grantees must have written approval from CPRIT prior to the purchase of any equipment. If the equipment is clearly defined in the grantee's budget submitted with the initiating award requirements, then approval of the grant award constitutes "prior approval" for the purchase. Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

**Continuation of funding is contingent upon the timely receipt of these reports.** Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

# 12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703, for specific requirements regarding the demonstration of available funding.

# 13. CONTACT INFORMATION

## 13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff members are not in a position to answer questions regarding scientific aspects of applications.

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

## 13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Director of Academic Research.

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

# Third Party Observer Report

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.4 Academic Research Recruitment Review Panel
# (23.4_SRC_REC)
# Observation Report

| | |
|---|---|
| Report No. | 2023-03-16 23.4_SRC_REC |
| Program Name: | Academic Research |
| Panel Name: | 23.4 Academic Research Recruitment Review Panel (23.4 _SRC_REC) |
| Panel Date: | March 16, 2023 |
| Report Date: | March 20, 2023 |

## *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 23.4 Academic Research Recruitment Review Panel (23.4_SRC_REC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on March 16, 2023.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed
- Panelists: One (1) panel chair, and five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) Conflicts of Interest (COIs) identified prior to and/or during the meeting. Conflicts of Interest were excluded from discussions concerning applications for which there was a conflict.

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

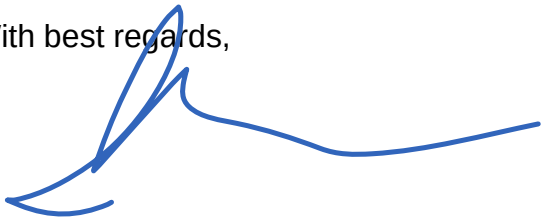
## *CONCLUSION*

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

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

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

With best regards,



Mara Ash, CIA, CGAP, CGFM, 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 23.4

Awards Announced at the May 17, 2023, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 23.4 include: *Recruitment of Established Investigators* and *Recruitment of First-Time, Tenure-Track Faculty Members.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

| Application ID | Principal Investigator | Organization | Conflict Noted by Reviewer |
|---|---|---|---|
| **Applications considered by the PIC and Oversight Committee:** | | | |
| RR230032 | W. P. Andrew Lee | The University of Texas Southwestern Medical Center | E. Fearon |
| **Applications not considered by the PIC or Oversight Committee:** | | | |
| RR230028 | Luay Nakhleh | Rice University | M. Pomper |

# De-Identified Overall Evaluation Scores

# Recruitment of First-Time, Tenure-Track Faculty Members

Academic Research Recruitment Cycle 23.4

| Application ID | Final Overall Evaluation Score |
|---|---|
| RR230031* | 1.0 |
| c[a] | 2.4 |
| d | 4.8 |

[a] The Scientific Review Council (SRC) recommended this application to the Program Integration Committee; however, the application was withdrawn by the applicant prior to the PIC meeting.

* Recommended for funding.

# Final Overall Evaluation Scores and Rank Order Scores

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

**Ludwig Institute for Cancer Research Ltd**

**Richard D. Kolodner Ph.D.**

Head, Laboratory of Cancer Genetics
San Diego Branch

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

**rkolodner@health.ucsd.edu**

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

**T** 858 534 7804
**F** 858 534 7750

April 14, 2023

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

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

Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on on March 16, 2023 (Cycle 23.4) to review and finalize applications submitted to CPRIT under the Recruitment of Established Investigator and Recruitment of First-Time, Tenure Track Faculty Members RFA mechanisms.

The SRC recommends four applications, which are inlcuded on the attached list. The recommended funding amounts and the overall evaluation scores are stated for the grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $16,000,000

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

Sincerely yours,

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

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

| Rank | ID | Award Mechanism | Final Overall Score | Application Title | Candidate | Organization | Budget |
|---|---|---|---|---|---|---|---|
| 1 | RR230031 | RFTFM | 1.0 | Nomination of Dian Yang, Ph.D. for a CPRIT Recruitment of a First-Time Tenure-Track Faculty Member Award Investigator | Dian Yang | The University of Texas Southwestern Medical Center | $2,000,000 |
| 2 | RR230032 | REI | 1.8 | Nomination of Yuan Zhu, Ph.D. for a CPRIT Recruitment of an Established Investigator Award | Yuan Zhu | The University of Texas Southwestern Medical Center | $6,000,000 |
| 3 | RR230029 | REI | 2.0 | Recruitment of Established Investigators - Dr. King | Michael King | Rice University | $6,000,000 |
| 4 | RR230024 | RFTFM | 2.4 | First-Time, Tenure-Track: Dr. Esteban Orellana | Esteban Orellana | Baylor College of Medicine | $2,000,000 |

RFTFM- Recruitment of First-Time Tenure Track Faculty
REI- Recruitment of Established Investigators

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application RR230029**
**Recruitment of Established Investigators**
**Nomination of Michael R. King, Ph.D.**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received four applications in response to this RFA during cycle 23.4. 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."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Mélanie Richardson
Notary Public, State of Texas

Melanie Richardson
Notary Public, State of Texas
Comm. Expires 10/08/2026
Notary ID 13175770-3

# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:24 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Recruitment
**MECHANISM:** Recruitment of Established Investigators
**APPLICATION ID:** RR230029
**APPLICATION TITLE:** Recruitment of Established Investigators - Dr. King
**APPLICANT NAME:** Nakhleh, Luay
**ORGANIZATION:** Rice University
**PANEL NAME:** Recruitment FY23_Cycle 4

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA Approved by CSO** | **06/21/2022** | 10/07/2022 |
| | **RFA published in Texas.gov eGrants** | **06/21/2022** | 10/07/2022 |
| | **CPRIT Application Receipt Cycle opened** | **12/21/2022** | 04/05/2023 |
| | **CPRIT Application Receipt Cycle closed** | **02/21/2023** | 04/05/2023 |
| | **Date application submitted** | **02/20/2023** | 04/05/2023 |
| | **Method of submission** | **CARS** | 04/05/2023 |
| | **Within receipt period** | **YES** | 04/05/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **N/A** | 04/05/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 04/05/2023 |
| | **Assigned to primary reviewers** | **03/02/2023** | 04/05/2023 |
| | **Applicant notified of review panel assignment** | **N/A** | 04/05/2023 |
| | **Primary Reviewer 1 COI signed** | **03/01/2023** | 04/05/2023 |
| | **Primary Reviewer 2 COI signed** | **02/24/2023** | 04/05/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **03/13/2023** | 04/05/2023 |
| | **Primary Reviewer 2 critique submitted** | **03/14/2023** | 04/05/2023 |
| | **COI indicated by non-primary reviewer** | **NONE** | 04/05/2023 |
| | **COI recused from participation** | **N/A** | 04/05/2023 |
| | **Discussed at Peer Review Meeting** | **YES** | 04/05/2023 |
| | **Peer Review Meeting** | **03/16/2023** | 04/05/2023 |
| | **Post review statements signed** | **03/27/2023** | 04/05/2023 |
| | **Third Party Observer Report** | **03/20/2023** | 04/05/2023 |
| | **Score report delivered to CSO** | **03/24/2023** | 04/05/2023 |
| | **Recommended for SRC review** | **YES** | 04/05/2023 |
| **Final SRC Recommendation** | **COI indicated by SRC member** | **NONE** | 04/05/2023 |
| | **COI recused from participation** | **N/A** | 04/05/2023 |
| | **SRC Meeting** | **03/16/2023** | 04/05/2023 |
| | **Third Party Observer Report** | **03/20/2023** | 04/05/2023 |
| | **Recommended for grant award** | **YES** | 04/05/2023 |
| | **SRC Chair Notification to PIC and OC** | **04/14/2023** | 04/21/2023 |
| **PIC Review** | **Candidate not accepted position prior to SRC date** | **YES** | 05/03/2023 |
| | **COI indicated by PIC member** | **None** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **05/03/2023** | 05/03/2023 |
| | **Recommended for grant award** | **YES** | 05/03/2023 |
| **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** | |

CPRIT maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application RR230031**
**Recruitment of First-Time, Tenure-Track Faculty Members**
**Nomination of Dian Yang, M.D.**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received three applications in response to this RFA during cycle 23.4. This application was assigned to the Scientific Review Council (SRC) for review. The SRC recommended two applications from this mechanism; however, one application was withdrawn by the applicant prior to the PIC meeting. 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."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Melanie Richardson
Notary Public, State of Texas

Melanie Richardson
Notary Public, State of Texas
Comm. Expires 10/08/2026
Notary ID 13175770-3

# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:24 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Recruitment
**MECHANISM:** Recruitment of First-Time, Tenure-Track Faculty Members
**APPLICATION ID:** RR230031
**APPLICATION TITLE:** Nomination of Dian Yang, Ph.D. for a CPRIT Recruitment of a First-Time Tenure- Track Faculty Member Award Investigator
**APPLICANT NAME:** Lee, W. P. Andrew
**ORGANIZATION:** The University of Texas Southwestern Medical Center
**PANEL NAME:** Recruitment FY23_Cycle 4

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA Approved by CSO** | **06/21/2022** | 10/07/2022 |
| | **RFA published in Texas.gov eGrants** | **06/21/2022** | 10/07/2022 |
| | **CPRIT Application Receipt Cycle opened** | **12/21/2022** | 04/05/2023 |
| | **CPRIT Application Receipt Cycle closed** | **02/21/2023** | 04/05/2023 |
| | **Date application submitted** | **02/20/2023** | 04/05/2023 |
| | **Method of submission** | **CARS** | 04/05/2023 |
| | **Within receipt period** | **YES** | 04/05/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **N/A** | 04/05/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 04/05/2023 |
| | **Assigned to primary reviewers** | **03/02/2023** | 04/05/2023 |
| | **Applicant notified of review panel assignment** | **N/A** | 04/05/2023 |
| | **Primary Reviewer 1 COI signed** | **02/24/2023** | 04/05/2023 |
| | **Primary Reviewer 2 COI signed** | **02/25/2023** | 04/05/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **03/14/2023** | 04/05/2023 |
| | **Primary Reviewer 2 critique submitted** | **03/07/2023** | 04/05/2023 |
| | **COI indicated by non-primary reviewer** | **NONE** | 04/05/2023 |
| | **COI recused from participation** | **N/A** | 04/05/2023 |
| | **Discussed at Peer Review Meeting** | **YES** | 04/05/2023 |
| | **Peer Review Meeting** | **03/16/2023** | 04/05/2023 |
| | **Post review statements signed** | **03/27/2023** | 04/05/2023 |
| | **Third Party Observer Report** | **03/20/2023** | 04/05/2023 |
| | **Score report delivered to CSO** | **03/24/2023** | 04/05/2023 |
| | **Recommended for SRC review** | **YES** | 04/05/2023 |
| **Final SRC Recommendation** | **COI indicated by SRC member** | **NONE** | 04/05/2023 |
| | **COI recused from participation** | **N/A** | 04/05/2023 |
| | **SRC Meeting** | **03/16/2023** | 04/05/2023 |
| | **Third Party Observer Report** | **03/20/2023** | 04/05/2023 |
| | **Recommended for grant award** | **YES** | 04/05/2023 |
| | **SRC Chair Notification to PIC and OC** | **04/14/2023** | 04/21/2023 |
| **PIC Review** | **Candidate not accepted asst. prof. tenure track position prior to SRC date** | **YES** | 05/03/2023 |
| | **COI indicated by PIC member** | **None** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **05/03/2023** | 05/03/2023 |
| | **Recommended for grant award** | **YES** | 05/03/2023 |
| **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** | |

CPRIT maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application RR230032**
**Recruitment of Established Investigators**
**Nomination of Yuan Zhu, M.D.**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received four applications in response to this RFA during cycle 23.4. 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."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Melanie Richardson
Notary Public, State of Texas

Melanie Richardson
Notary Public, State of Texas
Comm. Expires 10/08/2026
Notary ID 13175770-3

# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:24 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Recruitment
**MECHANISM:** Recruitment of Established Investigators
**APPLICATION ID:** RR230032
**APPLICATION TITLE:** Nomination of Yuan Zhu, Ph.D. for a CPRIT Recruitment of an Established Investigator Award
**APPLICANT NAME:** Lee, W. P. Andrew
**ORGANIZATION:** The University of Texas Southwestern Medical Center
**PANEL NAME:** Recruitment FY23_Cycle 4

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA Approved by CSO** | **06/21/2022** | 10/07/2022 |
| | **RFA published in Texas.gov eGrants** | **06/21/2022** | 10/07/2022 |
| | **CPRIT Application Receipt Cycle opened** | **12/21/2022** | 04/05/2023 |
| | **CPRIT Application Receipt Cycle closed** | **02/21/2023** | 04/05/2023 |
| | **Date application submitted** | **02/21/2023** | 04/05/2023 |
| | **Method of submission** | **CARS** | 04/05/2023 |
| | **Within receipt period** | **YES** | 04/05/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **02/27/2023** | 04/05/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 04/05/2023 |
| | **Assigned to primary reviewers** | **03/02/2023** | 04/05/2023 |
| | **Applicant notified of review panel assignment** | **N/A** | 04/05/2023 |
| | **Primary Reviewer 1 COI signed** | **02/24/2023** | 04/05/2023 |
| | **Primary Reviewer 2 COI signed** | **03/01/2023** | 04/05/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **03/14/2023** | 04/05/2023 |
| | **Primary Reviewer 2 critique submitted** | **03/14/2023** | 04/05/2023 |
| | **COI indicated by non-primary reviewer** | **Eric Fearon** | 04/05/2023 |
| | **COI recused from participation** | **YES** | 04/05/2023 |
| | **Discussed at Peer Review Meeting** | **YES** | 04/05/2023 |
| | **Peer Review Meeting** | **03/16/2023** | 04/05/2023 |
| | **Post review statements signed** | **03/27/2023** | 04/05/2023 |
| | **Third Party Observer Report** | **03/20/2023** | 04/05/2023 |
| | **Score report delivered to CSO** | **03/24/2023** | 04/05/2023 |
| | **Recommended for SRC review** | **YES** | 04/05/2023 |
| **Final SRC Recommendation** | **COI indicated by SRC member** | **Eric Fearon** | 04/05/2023 |
| | **COI recused from participation** | **YES** | 04/05/2023 |
| | **SRC Meeting** | **03/16/2023** | 04/05/2023 |
| | **Third Party Observer Report** | **03/20/2023** | 04/05/2023 |
| | **Recommended for grant award** | **YES** | 04/05/2023 |
| | **SRC Chair Notification to PIC and OC** | **04/14/2023** | 04/21/2023 |
| **PIC Review** | **Candidate not accepted position prior to SRC date** | **YES** | 05/03/2023 |
| | **COI indicated by PIC member** | **None** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **05/03/2023** | 05/03/2023 |
| | **Recommended for grant award** | **YES** | 05/03/2023 |
| **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** | |

CPRIT maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **To:** | OVERSIGHT COMMITTEE MEMBERS |
| **From:** | KEN SMITH, PHD, CHIEF PRODUCT DEVELOPMENT OFFICER |
| **Subject:** | FY 23.1 PRODUCT DEVELOPMENT RESEARCH AWARD RECOMMENDATIONS |
| **Date:** | MAY 11, 2023 |

**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: Resilience Texas, LLC, Allterum Therapeutics, LLC, 7 Hills Pharma, LLC, Pulmotect, Inc., OmniNano Pharmaceuticals, LLC, and OncoResponse. 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 Wayne Roberts 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. Since the last Oversight Committee meeting, I have worked with all 6 companies that were recommended for funding to address all contingencies and reduce the original proposed budgets.

Three recommendations made by the PDRC included contingencies associated with intellectual property (IP) ownership and licensing agreements. In addition, the PDRC specified a contract contingency for DP230064 and DP230071 related to the hiring of regulatory expertise/consultants. Contingencies related to clinical trial designs were included for DP230066. CPRIT enlisted assistance from our third-party due diligence consultants to assist with the review and resolution of contingencies related to clinical trial designs. I have reviewed and resolved all other contingencies.

Three of the six companies recommended for funding proposed reductions in personnel/salary, consulting, and subcontract costs. One company, DP230076, proposed to increase their matching fund to 1:1 and fully cover their indirect costs. Two companies have proposed to reduce the number of cohorts in their clinical trial while two other companies proposed to decrease the number of objectives funded by CPRIT. The companies will use their own funds or funding from other sources to address budget shortfalls. The total funding request for all 6 companies has been reduced to $59,081,927.

I will address the contingencies and budget changes at the meetings with the PIC and the Oversight Committee.

## FY 2023 Cycle 1 Award Recommendations

| Rank | ID | RFA | Company | Project | Score* | Budget |
|---|---|---|---|---|---|---|
| 1 | DP230079 | TNTC FULL | Resilience Texas, LLC dba CTMC | Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value-Added Biotech Partnerships | 2.3 | $9,100,000 |
| 2 | DP230062 | TTC FULL | 7 Hills Pharma LLC | 7HP349, a Small Molecule, Oral Integrin Activator to Treat Patients With anti-PD-1 Resistant Melanoma | 2.6 | $13,439,001 |
| 3 | DP230064 | SEED Ther. | OmniNano Pharmaceuticals LLC | IND-Enabling Studies of ONP-001: A Nano-Codelivery Formulation with Two Drugs of Distinct Mechanisms of Action for Treating Pancreatic Ductal Adenocarcinoma | 3.3 | $2,711,437 |
| 4 | DP230076 | TTC FULL | OncoResponse | OncoResponse OR502 anti-LILRB2 monoclonal antibody Phase 1-2 clinical study | 3.6 | $13,259,174 |
| 5 | DP230066 | TTC FULL | Pulmotect, Inc. | Improving Cancer Patient Outcomes by Activating Lung Innate ImmunityLutetium-177 for Use in Prostate Cancer Therapy | 3.3 | $8,851,165 |
| 6 | DP230071 | TTC FULL | Allterum Therapeutics, LLC | Clinical development of a novel CD127 antibody for treating patients with relapsed/refractory Acute Lymphoblastic Leukemia (ALL) | 2.6 | $11,721,150 |
| | | | | | **TOTAL** | **$ 59,081,927** |

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

## Background - FY 2023 Review Cycle 1

CPRIT released four FY 2023 Product Development Research RFAs and opened the portal to receive preliminary applications on a rolling basis beginning August 24. CPRIT received 60 preliminary applications on a rolling basis through January 20. Of the 60 preliminary applications submitted to CPRIT, 20 companies are currently located in states/countries outside of Texas, including California, Florida, Kansas, Massachusetts, Maryland, North Carolina, New Jersey, Virginia, Washington, India, and Sweden. Based on the decision of the preliminary review panels, CPRIT invited 29 companies to submit full applications. We received 14 full applications by the November 1 full application deadline. CPRIT moved forward the first 10 applications for review and deferred four applications until the next full application review cycle which will take place August 1. The ten companies in the first cycle included four applicants currently located out of state. The total budget request for the ten applications was $149,091,114. Following the due diligence meetings held January 13 – 20 to review the reports prepared for the six remaining companies, the review panels finalized scores and recommended each of the companies for funding. The PDRC convened January 23 to finalize the ranking and recommendations for the final six companies. The total funding request for the companies recommended by the PDRC is $82,456,660.

The total budget request for the final slate of companies recommended by the PDRC exceeded the remaining funds ($57,493,121) allocated for FY 2023 product development program awards. At my request, the Program Integration Committee (PIC) approved deferring final PIC action on the PDRC's recommendations until the May Oversight Committee meeting.

**Opening of the FY 2024 Review Cycle**

CPRIT will release the Product Development Research RFAs on May 1. The portal will be open to receive preliminary applications on a rolling basis until June 30. June 30 was selected as a deadline to provide applicants who receive full application invitations, time to complete their full application and submit them on the first full application deadline, August 1. Four deferred applications from FY2023 Cycle 1 will be reviewed during the August 1 (first) cycle in FY 2024. Due to scheduling and resource constraints, CPRIT has stated in the RFAs that we are limiting the number of full applications that the review panels will consider in Review Cycle 1 to the first fifteen applications received on or before the August 1 deadline, this total includes the four deferred applications from FY 2023 cycle 1.

**Product Development Research Priorities Addressed by the 23.1 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* |
|---|---|---|
| **4** | Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies | **$47,270,490** |
| **6** | Funding projects addressing large or challenging unmet medical needs | **$59,081,927** |
| **5** | Investing in early-stage projects where private capital is least available | **$49,981,927** |
| **5** | Stimulating commercialization of technologies developed at Texas institutions | **$47,360,777** |
| **5** | 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 | **$56,370,490** |
| **6** | Providing appropriate return on taxpayer investment | **$59,081,927** |

*Some proposed awards address more than one priority.

**Mechanism of Support and Product Development Research Objectives**

Applications submitted in the 23.1 review cycle responded to one of three 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 2023 Review Cycle 1

### *Resilience Texas LLC dba CTMC*
### *Proposed TNTC FULL Award for Product Development Research*

**Summary of Recommendation**

The PDRC recommends that the PIC and Oversight Committee approve a Texas New Technologies Company Full Award for Product Development Research to Resilience Texas LLC dba CTMC for $9,100,000.

Cell Therapy Manufacturing Center (CTMC) is a Houston-based joint venture between National Resilience Inc. and MD Anderson Cancer Center (MDACC) to accelerate cell therapy development. There has been a 10-fold increase in cancer cell therapy trials over the last decade. CTMC focuses on three areas to benefit patients and technology by building capacity and differentiated capabilities for retroviral vector (RVV) manufacturing, tumor infiltrating lymphocyte (TIL) platform improvement, and CAR-T process development strategy.

**CPRIT Product Development Research Priorities Addressed**

CTMC's proposed project addresses three of the six Product Development Research Priorities:

- Funding projects addressing large or challenging unmet medical needs;
- Stimulating commercialization of technologies developed at Texas institutions; and
- 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.

**Project Summary and Scientific Rationale**

Autologous cell therapies manufacturing process is fraught with bottlenecks that limit treatment access for many patients due to length of time and high production costs. CTMC's current scientific and structural advantages in autologous cell therapy includes a 60,000 SF facility adjacent to MDACC. The project will provide a vertically integrated approach to 1) accelerate novel therapies to the clinic (reduce time from research to clinical proof of concept) 2) provide a robust strategy to move products from clinical proof of concept to commercialization, and 3) drive down the long-term commercial cost of cellular therapy products.

There are few manufacturing centers that focus on retroviral vectors, and little to no development of downstream process development of the RVV. CTMC will utilize a two-pronged approach: optimized transient transfection to make RVV for a fast-to-clinic strategy as well as development of a robust clonal pools, selected clones, and downstream purification RVV process to support a streamlined approach for later stage therapies which will provide a reduced overall development timeline.

TIL therapy is a proven and effective option in melanoma, and much of the development of successful manufacturing processes done by the scientific staff that moved from MDACC to CTMC. The project will utilize CTMC's prior expertise in TIL optimization to improve the second phase of the process through final formulation. These improvements will develop a robust and broadly applicable potency assay that is currently lacking in the field, which will open doors for exploration of novel engineering in the TIL field, expansion to additional cancer indications.

Autologous cellular therapies require dedicated equipment, highly trained operators, and individual manufacturing for each patient. CAR-T processes are typically developed solely with healthy donor blood products and standard/unoptimized cryopreservation methods. CTMC proposes to develop scale-down models, accessing and incorporating patient samples during development with quicker and less costly evaluation of automated steps, and by developing data-driven methods for freezing products based on cryopreservation strategies.

The proposal provides that CTMC establish a robust and flexible center for retroviral vector (RVV) manufacturing in Texas; Expand platform expertise by optimizing tumor infiltrating lymphocyte (TIL) manufacturing and provide a differentiated process development approach for CAR-T manufacturing.

**Select Reviewer Comments**

**"***Major strengths of the application include the objectives, which have identified bottle necks in RRV, CAR-T, and TIL manufacturing and propose innovative strategies to overcome them. The close partnership with MD Anderson and a regulatory staff, which allows for essentially 1-stop preclinical to clinical development of cell-based therapeutics, is highly innovative."*

**"***This is a very innovative concept and structure potentially addressing some of the challenges in the cell and gene therapy space … builds permanent jobs in Texas and adds to the needed biotech infrastructure to create a true biotech/oncology ecosystem."*

*"The development plan indicates an opportunity to further research and develop a technology that will save time to get treatment to patients."*

## *Allterum Therapeutics, LLC*
## *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 Allterum Therapeutics, LLC for $$11,721,150.

Allterum Therapeutics LLC is a Houston-based preclinical company formed around research conducted at National Cancer Institute of a monoclonal antibody, 4A10, against CD127 as a treatment for acute lymphoblastic leukemia (ALL). CD127 is a subunit for both the interleukin-7 receptor (IL-7R) and the TSLP receptor, which are expressed on T-Cell ALL and pre-B Cell ALL, respectively. 4A10 binds CD127 and exerts its anticancer activity by a dual mechanism: inhibition of IL-7 signaling and cytotoxicity via ADCC mediated by its IgG1 Fc region. 4A10's anti-cancer activity in ALL has been demonstrated both in vitro and in vivo in multiple labs, including patient-derived xenograft (PDX) models.

**CPRIT Product Development Research Priorities Addressed**

Allterum Therapeutics, Inc.'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; and
- Providing appropriate return on taxpayer investment.

**Project Summary and Scientific Rationale**

There are about 7,000 cases of ALL in the U.S. each year with ~1,600 deaths. ~80% of ALL patients are children, making it the most common childhood cancer in the U.S. ~80% of ALL patients have pre-B cell ALL (B-ALL) and ~20% have T-cell ALL (T-ALL). ALL treatment is a relative success story in cancer. Both B-ALL and T-ALL patients receive a similar first-line regimen, to which ~85% respond. Several options exist for patients with B-ALL who progress after first-line therapy, but a third will still progress or be unable to tolerate available treatments. Patients with T-ALL who progress have an even poorer prognosis, with no approved targeted second-line options. Patients with relapsed or refractory (r/r) ALL have poor outcomes with a 15-35% five-year survival, and are the initial focus of our development.

4A10 is expected to be well tolerated and active even in relapsed disease, it would be attractive to patients who have failed or cannot tolerate other available therapies. The clinical goal of the project is to get a complete response without minimal residue disease making the patient eligible for a potentially curative stem cell transplant. The long-term goal is to expand the label to add 4A10 to standard first-line therapy to increase effectiveness and/or decrease toxicity.

A prior CPRIT Seed award supported scale up 4A10 manufacturing, conduct early toxicological studies, develop clinical protocol, and obtain pre-IND guidance from FDA. 4A10 has received orphan drug and pediatric rare disease designation in ALL. The proposal provides that Allterum will Manufacture of Drug Substance (DS) and Drug Product (DP) under GMP; Perform Pivotal GLP Toxicology Studies to support IND filing; Submit IND and IRB filings and initiate clinical trial site(s) for the Phase I/IIA Clinical Trial of 4A10 in Patients with relapsed/refractory Acute Lymphoblastic Leukemia (r/r ALL); and Conduct First-in-Human Phase I/IIA Clinical Trial for 4A10 in r/r ALL patients.

**Select Reviewer Comments**

*"There is an unmet need for treating recurring or resistant forms of ALL. This applicant is proposing the development of a product to provide benefit to these patients with a low-toxicity product … The applicant has had a pre-IND meeting with the FDA and has incorporated the FDA recommendations into their study design, ie, monotherapy for 28 days. Additionally, the applicant indicates that they have already received orphan drug and pediatric rare disease designation for 4A10 in ALL."*

*"This proposal is very Texas-centric, and the conduct of this work will further both CPRIT's goals and successes."*

*"Novel effective treatment options for relapsed/refractory ALL are needed, and the intended product that targets CD127 could satisfy an unmet need for treatment."*

## *7 Hills Pharma LLC*
## *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 7 Hills Pharma LLC for $13,439,001.

7 Hills Pharma LLC is a Houston-based company which is developing 7HP349 which is a first-in-class, oral, small molecule, positive allosteric modulator of integrins critical for immune surveillance (immune cell priming, trafficking and effector functions) that may increase the effectiveness of CPI, with a low risk of elevated immunotoxicities, in PD-1 resistant cancers.

**CPRIT Product Development Research Priorities Addressed**

7 Hills LLC proposed project addresses six of the six Product Development Research Priorities:

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

**Project Summary and Scientific Rationale**

7HP349 as systemic drug has been shown to have single-agent antitumor activity, is synergistic with PD-(L)1, aCTLA-4, and immunogenic doses of radiation with tumor-selective homing of

antigen-specific T cells. The priming dose, schedule, and plasma exposures have been defined in multiple mouse tumor and infectious disease models. 7HP349 has been shown not to increase immunotoxicies.

In a Phase I healthy volunteer study, 7HP349 was orally bioavailable with a safety margin of >10x based on the optimal pharmacokinetic (PK) exposures with a minor positive food effect. The single dose and repeat dose PK were non-linear, and the T ½ of ~20h supported once-daily dosing. 7HP349 doses of 100-300 mg will be dose escalated in combination with ipilimumab and nivolumab.

7 Hills has developed scalable, low-cost manufacturing processes and estimate ambient stability of 5 and 3 years for the 7HP349 Drug Substance (DS) and Product (DP). 16 kg of cGMP DS and 30,000 capsules of DP have been produced and will be ready for clinical use in 2Q2023.

US FDA has granted 7HP349 Orphan Drug designation for treatment of malignant melanoma stages IIB to IV and Fast Track designation for 7HP349 in combination with a CTLA-4 inhibitor for the treatment of patients with unresectable or metastatic *MM* following prior PD-1 inhibitor treatment.

The proposed project aims to establish target-centric patient selection biomarker; manufacture and release of cGMP 7HP349 Drug Product(s) (DP), and complete registrational ICH stability programs; complete the 7HP111, Phase Ib/IIa clinical trial to determine the safety and efficacy of oral 7HP349 in combination with ipilimumab followed by nivolumab in patients with locally advanced or metastatic malignancies (melanoma, HNSCC, NSCLC) resistant to or relapsing after PD-1 inhibitor therapy.

**Select Reviewer Comments**

*"The application states that over 40% of patients with metastatic melanoma are resistant to checkpoint inhibitor therapies. An oral medication that can increase the effectiveness of current immunotherapies without an increase in toxicities would be of benefit to such patients."*

*"7 Hills Pharma is pursuing an unmet medical need with a novel mechanism targeting resistant metastatic melanoma patients with aPD-1 resistance by enhancing ICI effectiveness with 7HP349, a first-in-class, oral, small-molecule, positive allosteric modulator of integrins critical for immune cell priming, T cell trafficking and effector functions."*

*"7 Hills Pharma has presented impressive in vivo pharmacodynamic effects with 7HP349 including significant inhibition of tumor growth and increased response rate in combination with aPD-1 and aCTLA-4 immune checkpoint inhibitors and effected an increase in the recruitment of CD4 and CD8 T cells into the tumor. "*

## *OncoResponse*
## *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 OncoResponse for $13,259,174.

OncoResponse is a Seattle-based company which is developing OR502 which is a humanized monoclonal antibody for treatment of advanced human malignancies. The target of OR502 is the leukocyte immunoglobulin-like receptor-2/immunoglobulinlike transcript-4 (LILRB2/ILT4) protein which is expressed on the surface of certain immune cells known to play a role in mmune response to cancer. OR502 disrupts immuoinhibitory actions of LILRB2, leading to immune stimulation and potentiation of anti-cancer responses.

**CPRIT Product Development Research Priorities Addressed**

OncoResponse proposed project addresses six of the six Product Development Research Priorities:

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

**Project Summary and Scientific Rationale**

OR502 is a humanized monoclonal antibody that binds with high affinity and specificity to an epitope on LILRB2 distinct from all other clinical candidates, including MK-4830. OR502 demonstrates specific binding to myeloid cells, no binding to a panel of other immune cells, and potently blocks the interaction of LILRB2 with HLA-G and other HLA-class I molecules. In pre-clinical studies, OR502 demonstrates superior characteristics versus competitors. OR502 outperforms MK-4830 in restoring $CD8^+$ T-cell proliferation, interferon gamma and perforin secretion in M2c/$CD8^+$ T cell coculture assay and rescues interferon gamma production in M2c/Exhausted $CD8^+$ T cell coculture assays. OR502 has 2-pronged functionality, as it reduces

the immunosuppressive phenotype of existing tumor associate macrophages (TAMs) and prevents development of new immunosuppressive TAMs.

OncoResponse is developing an OR502-expressing cell line, cell culture process, purification process, analytical methods, and formulation and completed a manufacturability assessment which showing excellent characteristics.

OR502 will be developed for the treatment of solid tumors. The development plan will first determine the safe dose of OR502 in subjects with advanced solid malignancies for which no standard therapies exist, and then evaluate additional safety and potential activity in tumor-specific expansion cohorts. The Phase 1 study will use an efficient dose-escalation design to rapidly determine a safe and potentially efficacious dose and schedule. Concurrent with monotherapy dose escalation, combination cohorts with an anti-PD-(L)1 will be enrolled to evaluate safety of OR502 in combination.

OncoResponse's proposal provides for completing all IND-enabling studies for OR502 and file NDA with FDA; initiating Phase 1A clinical trials to assess safety and dose level; completing Phase 1A trials and establish RP2D (monotherapy and in combination with anti-PD-1; initiating dose-expansion for 2 indications (monotherapy and in combination); initiating monotherapy biology cohort and conduct additional biomarker analysis and assessing initial ORR for initial patients in expansion and biology cohorts

**Select Reviewer Comments**

*The management team is very strong and experienced, including the CEO who has many years of experience in raising venture capital and mergers and acquisitions. The CMO is a medical oncologist who trained at NIH and has many years of experience in the pharmaceutical industry. The CSO is experienced in biomarker development and generating preclinical data.*

*This is a validated target with potential for addressing important unmet/emerging needs in a variety of cancers.*

*This is a very strong resubmission of an application focused on addressing the unmet need in ICI response.*

## *Pulmotect, 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 Pulmotect Inc. for $8,851,165.

Pulmotect, Inc. is a Houston-based company which is developing an immunomodulatory technology to treat and prevent respiratory infections in immunocompromised cancer patients to improve cancer patient outcomes. PUL-042 inhalation solution contains two active ingredients, which act synergistically on Toll-like receptors to stimulate pulmonary epithelial innate immunity and protect against a wide range of pathogens.

**CPRIT Product Development Research Priorities Addressed**

Pulmotect, Inc. proposed project addresses six of the six Product Development Research Priorities:

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

**Project Summary and Scientific Rationale**

Respiratory infections are caused by a variety of pathogenic organisms including viruses, bacteria, and fungi. Cancer patients are highly susceptible to respiratory infection and potentially lethal pneumonia due to suppressed *adaptive* immunity. Pneumonia is second only to the underlying cancer in causing death in cancer patients.

Cancer patients still have intact respiratory epithelium that can respond to stimuli. By stimulating these *innate epithelial immune responses* in the lung and enhancing the ability to fight off invading pathogens, patients can be protected from pulmonary infections, thereby reducing morbidity and mortality. PUL-042, is administered by inhalation and activates the lung epithelial innate defense mechanisms through stimulation of specific lung epithelial Toll-like receptors providing broad protection against invading pathogens. Extensive *in vitro* and *in vivo* preclinical

experiments and toxicology studies have demonstrated safety and broad protection against pathogens. PUL-042 has clinical evidence of anti-viral activity against the SARS-CoV-2 virus in a Phase 2 clinical trial. Data in more than 200 PUL-042 treated subjects demonstrate safety and clinical proof of concept thereby increasing the probability of successful development.

Pulmotect proposes to Initiate a Phase 2 Clinical Trial; Complete Patient Enrollment and Complete Final Study Report:

**Select Reviewer Comments**

*Pulmonary infection (pneumonia) among immunocompromised patients is a well established area of unmet clinical need, accounting for the proximate cause of mortality among many hospitalized patients. A "pathogen" agnostic therapeutic modality would have widespread applications.*

*Given the high mortality from pneumonia in immunocompromised cancer patients, the challenges of rapid diagnosis and treatment of one or multiple lung infections and the promise of prophylaxis and/or treatment of viral, bacterial or fungal infections by stimulation of innate immunity in the lung, there is tremendous unmet need and potential for PUL-042.*

## *OmniNano Pharmaceuticals LLC*
## *Proposed SEED Award for Product Development Research*

**Summary of Recommendation**

The PDRC recommends that the PIC and Oversight Committee approve a SEED Award for Product Development Research to OmniNano Pharmaceuticals LLC for $2,711,437.

OmniNano Pharmaceuticals LLC is a Missouri City-based company which is developing a platform using polymeric micellar nanocarrier to codeliver distinctly different drugs to tumors which thereby increases therapeutic concentrations of individual drugs in a simultaneous manner.

**CPRIT Product Development Research Priorities Addressed**

OmniNano Pharmaceuticals LLC proposed project addresses four of the six Product Development Research Priorities:

- 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;
- Providing appropriate return on taxpayer investment.

**Project Summary and Scientific Rationale**

Pancreatic ductal adenocarcinoma (PDAC) has a 5-year survival rate of just 11.5% and an overall median survival time of <1 year with the current standard-of-care treatments. This proposal seeks to develop a polymeric micelle-based solution to PDAC based on a micellar co-formulation delivery platform for cyclopamine (CPA), a naturally-occurring compound capable of depleting cancer stem cells, and paclitaxel (PTX), a cytotoxic chemotherapeutic agent that eliminates proliferating cancer cells. In preclinical studies, the polymeric micelles containing both CPA and PTX, named ONP-001, significantly prolonged the median survival of transgenic KPC mice that harbor certain mutations. In a randomized study, ONP-001 increased median survival of mice by 8-fold compared to nab-paclitaxel and by 7-fold compared to gemcitabine. ONP-001 increased the area of benign pancreatic tissue by 270% and substantially reduced poorly differentiated or moderately differentiated tumor cells.2 The strong anti-PDAC efficacy was achieved with a minimal systemic toxicity. ONP-001 overcomes poor drug delivery of therapeutic agents by continuously remodeling tumor stroma to normalize tumor blood vessels and alleviate tumor hypoxia, which leads to increased ONP-001 delivery via a positive reinforcing feedback loop for delivery efficiency. The goals of the proposed project are to manufacture ONP-001 under current Good Manufacture Practice (cGMP) guidance, to conduct GLP-toxicity and toxicokinetic studies (rodents and non-rodents), and to prepare a robust IND (investigational new drug) package to be filed with the FDA.

**Select Reviewer Comments**

*ONP-01 is an innovative product with potential for effective treatment of PDAC.*

*The management team has experience in managing clinical research projects in nanomedicine, as well as on the development of novel drug-delivery systems for selective delivery of diagnostic and therapeutic agents. The team also includes an expert in pharmacokinetics (PK) and pharmacodynamics (PD) of drug formulations.*

*Strong preclinical data that demonstrate feasibility of clinical approach.*

January 30, 2023

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

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

Dr. Patel and Mr. Roberts,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 23.1 grant award cycle. The PDRC convened on January 23, 2023 and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Resilience Texas LLC dba CTMC, Allterum Therapeutics, LLC, 7 Hills Pharma, LLC, Pulmotect, Inc., OmniNano Pharmaceuticals LLC, OncoResponse. The attached table reflects the ranked award recommendation for the six (6) grant applications that CPRIT would like deferred to the May 2023 Oversight Committee meeting.

The PDRC did not make any changes to timelines or budgets for the six (6) projects recommended for funding. However, four (4) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP230071, DP230076, and DP230079 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP230066 related to clinical data and statistical analysis. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

# FY23.1 Product Development Review Council Recommendations

| Ranking | ID | Mechanism | Type | PI Last Name | Application Title | Organization | Score from Due Diligence | Budget |
|---|---|---|---|---|---|---|---|---|
| 1 | DP230079 | TNTC | New | Bock, J | Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value-Added Biotech Partnerships | Resilience Texas LLC dba CTMC | 2.3 | $12,000,000 |
| 2 | DP230062 | TTC | New | Lewis, L | 7HP349, a Small Molecule, Oral Integrin Activator to Treat Patients With anti-PD-1 Resistant Melanoma | 7 Hills Pharma LLC | 2.6 | $18,679,381 |
| 3 | DP230064 | SEED Therapeutics | New | Ma, G | IND-Enabling Studies of ONP-001: A Nano-Codelivery Formulation with Two Drugs of Distinct Mechanisms of Action for Treating Pancreatic Ductal Adenocarcinoma | OmniNano Pharmaceuticals LLC | 3.3 | $2,999,858 |
| 4 | DP230076 | TTC | New | Stocks, C | OncoResponse OR502 anti-LILRB2 monoclonal antibody Phase 1-2 clinical study | OncoResponse | 3.6 | $19,326,953 |
| 5 | DP230066 | TTC | Resubmission | Scott, B | Improving Cancer Patient Outcomes by Activating Lung Innate Immunity | Pulmotect, Inc. | 3.3 | $12,445,092 |
| 6 | DP230071 | TTC | Resubmission | Varadhachary, A | Clinical development of a novel CD127 antibody for treating patients with relapsed/refractory Acute Lymphoblastic Leukemia (ALL) | Allterum Therapeutics, LLC | 2.6 | $17,005,376 |

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

May 12, 2023

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 six companies that the Oversight Committee will consider for product development research grant awards at its May 17, 2023, 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,

Wayne Roberts
CPRIT Chief Executive Officer

Cancer Prevention & Research
Institute of Texas

# CEO Affidavit
# Supporting Information

**Product Development Research**
**FY 2023—Cycle 1**
***SEED Awards for Product Development Research***

# Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS
# RFA C-23.1-SEED

## SEED Awards for Product Development Research

**Please also refer to the Instructions for Applicants document, which CPRIT will post August 24, 2022**

**Preliminary Application Receipt Opening Date:** August 24, 2022

**Full Application Receipt Closing Date:** May 1, 2023

**FY 2023**

Fiscal Year Award Period

September 1, 2022-August 31, 2023

## TABLE OF CONTENTS

# RFA VERSION HISTORY

Rev 8/24/2022 RFA release

Rev 10/11/2022 Section 6.4 – Preliminary and Full Application Submission Deadlines

- Edited to clarify how many full applications will be reviewed in the first full application review cycle

Section 8.3 – Goals and Objectives (G&Os)

- Edited to clarify that G&Os in the full application should not vary significantly from the aims presented in the preliminary application

Section 8.12 – Budget

- Edited to clarify that the total budget included in the full application must not vary significantly from the anticipated budget request included in the applicant's preliminary application

# 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 at any time, which a panel of experts will review within 3 to 5 weeks of receiving the submission. If the preliminary application demonstrates sufficient scientific merit and appears to be an appropriate fit for CPRIT's portfolio, CPRIT will invite the company 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. For planning purposes, CPRIT's review schedule links panel presentation dates and final award decisions to the 3 application submission deadlines offered per CPRIT's fiscal year (September 1-August 31).

Applicants may request up to $3 million in funding so long as the request is appropriate to the work proposed. 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 contemporaneous 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." 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 FY 2023 are as follows:

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

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 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 proof of concept
- 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

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 one 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. Resubmission Policy

For the FY 2023 review cycle, CPRIT will consider the company's first preliminary application, and subsequent full application if CPRIT invites the company to submit a full application, as a new application, even if the company previously applied prior to August 24, 2022.

A company may resubmit a preliminary application 1 time (for a total of 2 submissions) during the FY 2023 review cycle. 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. 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 2-step process to review company projects proposed for funding. An integrated panel of individuals with expertise in biotechnology and basic/translational/clinical cancer research as well as regulatory approval processes will review all applications. Cancer patient advocates also participate in the review of full applications.

All 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. 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.

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.

The company may submit a preliminary application at any 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. The review process ends after preliminary review for those applicants not invited to submit a full application.

Absent unusual circumstances, CPRIT will notify the applicant of the outcome of the preliminary review within 3 to 5 weeks.

## 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 also convenes virtually for the applicant to present the application in person and respond to reviewers' questions.

### 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 aspects, manufacturability, and market assessments. The applicant should be prepared to provide CPRIT with any correspondence that the company has conducted with regulatory agencies (eg, the FDA).

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 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
- Proposed Integrated Product Development Plan (IPDP)
- 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 one 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.** Applicants must create a CARS user account to generate and submit the application. The *Instructions for Applicants* associated with this RFA provide information about establishing a user account.

## 6.2. Invitations to Submit Full Applications Valid Only for the FY 2023 Review Process

The invitation to submit a full application is valid only for the FY 2023 review cycle. This means that a company must submit its full application no later than May 1, 2023, for CPRIT to consider the project for FY 2023 award funding. An applicant invited to submit a full application in FY 2023 but does not do so must restart the review process in a future cycle by resubmitting the preliminary application. However, the resubmission will not count against the limit in CPRIT's resubmission policy.

## 6.3. CPRIT May Elect to Close the FY 2023 Review Cycle Early If Funds Are Unavailable

Applicants should be cognizant that CPRIT has limited funds available to fund Product Development Awards (approximately $70 million for the FY 2023 review cycle). CPRIT may cease accepting applications for the FY 2023 review cycle and/or defer applications to the FY 2024 review cycle if the amount approved for FY 2023 Product Development Awards exceeds $70 million prior to the close of the FY 2023 review cycle.

## 6.4. Preliminary and Full Application Submission Deadlines; Other Key Dates

Preliminary Applications: An applicant may submit a preliminary application via CARS at any time on or after August 24, 2022.

Full Applications: CPRIT will convene review panels up to 3 times during the FY 2023 review process for in-person presentations of full applications. Invited applicants may elect to submit the full application by one of the deadlines listed below, and the next available review panel will consider application. Key dates for the FY 2023 review cycles:

| **FY 2023 Review Cycle 1** | |
|---|---|
| Full Application Deadline | November 1, 2022; 4:00 PM central time |
| In-Person Presentation | Week of December 12, 2022 |
| Due Diligence | December 2022-January 2023 |
| Oversight Committee Meeting | February 15, 2023 |

| **FY 2023 Review Cycle 2** | |
|---|---|
| Full Application Deadline | February 1, 2023; 4:00 PM central time |
| In-Person Presentation | Week of March 13, 2023 |
| Due Diligence | March-April 2023 |
| Oversight Committee Meeting | May 17, 2023 |

| **FY 2023 Review Cycle 3** | |
|---|---|
| Full Application Deadline | May 1, 2023; 4:00 PM central time |
| In-Person Presentation | Week of June 12, 2023 |
| Due Diligence | June-July 2023 |
| Oversight Committee Meeting | August 16, 2023 |

CPRIT will endeavor to assign all applications received by the review cycle deadline to the next available in-person presentation panel. However, if the number of applications received by the deadline exceeds the review panel's ability to provide a thorough, fair review, CPRIT will use its discretion to assign the application to a future review panel. Due to schedule constraints, CPRIT has the capacity to review no more than 10 full applications in the first review cycle (full application deadline November 1, 2022). If the number of full applications submitted by the November 1 deadline exceeds 10, then CPRIT will review the first 10 full applications submitted

in CARS as reflected by the date/time of the submission. For those full applications submitted in the first review cycle but not reviewed, CPRIT will defer the review to the second review cycle (full application deadline February 1, 2023).

## 6.5. Submission Deadline Extensions

In-person panel presentation schedules are set in advance and do not accommodate receipt of a 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 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 a minimum of 5 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.

## 6.6. 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 make the payment by check or money order payable to "Cancer Prevention and Research Institute of Texas." Indicate the application ID and the name of the submitter on the check. CPRIT will not accept electronic and 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. 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 vs normal cells; potency vs competitive agents)
h. In vivo preclinical efficacy characterization (list animal models tested and describe their translational relevance to initial target indication[s]; effectiveness vs SOC; tumor growth inhibition vs 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, agency interactions to date 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

### 7.2. 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.

### 7.3. 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.

## 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.

### 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 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 one 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 vs normal cells; potency vs competitive agents)
h. In vivo preclinical efficacy characterization (list animal models tested and describe their translational relevance to initial target indication[s]; effectiveness vs SOC; tumor growth inhibition vs 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 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. 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, agency interactions to date 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

## 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 1 page)

If the applicant submitted a preliminary or full application to CPRIT prior to August 2022 or if the applicant is resubmitting a preliminary or full application already submitted in the FY 2023 review cycle, upload a summary of the 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 application 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.

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.

**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 (maximum 10 pages)

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. Product and Market

Provide an overview of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the SOC, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc. Information on patient populations and market segments is helpful.

### 8.9.2. Competition and Value Proposition

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

### 8.9.3. Clinical and Regulatory Plans

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.

### 8.9.4. Commercial Strategy

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

### 8.9.5. Risk Analysis

Describe the specific risks inherent to the product plan and how they would be mitigated. Key risk issues typically include efficacy versus competitors, toxicity, clinical trials, FDA approval, dosage and delivery, CMC synthesis, changing competitive environment, etc.

### 8.9.6. Funding to Date

Provide an overview of the funding received, including a list of funding sources and a comprehensive capitalization table that should comprise all parties who have investments, stock, or rights in the company. A template exemplifying an appropriate capitalization table is provided among the application materials and MUST be used when completing your application. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous. NOTE: This may exceed this 1-page limit if necessary.

### 8.9.7. Intellectual Property (IP)

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.

### 8.9.8. Management Team and Key Personnel

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" 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. 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 FY 2023 annual salary is $200,000. An individual may request salary proportional to the percent effort up to a maximum of $200,000. 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 $200,000. CPRIT may revise the FY 2023 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 $1 of funds under the company's control for every $2 of CPRIT grant award funds.
- A company approved for one or more CPRIT product development grants that together total a commitment of more than $20 million must increase their matching fund obligation to $1 for every $1 contributed by CPRIT.
  The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under CPRIT's matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.
- A company approved for 1 or more CPRIT product development grants that together total a commitment of more than $30 million must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

# 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:** | Help@CPRITGrants.org |
| **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: Target Product Profile (TPP)

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? 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 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 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)
# 23.1 Product Development Research Preliminary Application Review 1.1 (23.1 _PDPRE 23.1 - 1.1)
# Observation Report

| | |
|---|---|
| Report No. | 2022-09-22 23.1_PDPRE 23.1 - 1.1 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review 1.1 (23.1 _PDPRE 23.1 - 1.1) |
| Panel Date: | September 22, 2022 |
| Report Date: | September 28, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Preliminary Application Review 1.1 (23.1_PDPRE 23.1 - 1.1) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on September 22, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and three (3) PDRC members
- 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.

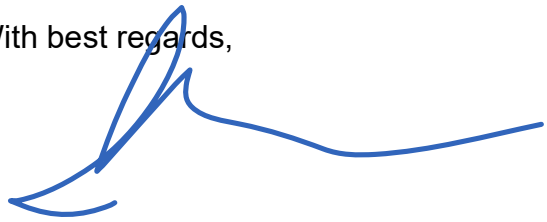
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.2)
# Observation Report

| | |
|---|---|
| Report No. | 2022-09-26 23.1_PDPRE 2.2 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 2.2) |
| Panel Date: | September 26, 2022 |
| Report Date: | September 28, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.2) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on September 26, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and one (1) application was not discussed
- Panelists: One (1) panel chair, three (3) PDRC members
- 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 (COIs) identified prior to and/or during the meeting.

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

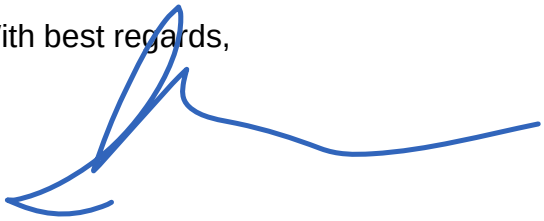
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 1.4)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-06 23.1_PDPRE 1.4 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 1.4) |
| Panel Date: | October 6, 2022 |
| Report Date: | October 11, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 1.4) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on October 6, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed
- Panelists: One (1) panel chair, and three (3) PDRC members
- 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.

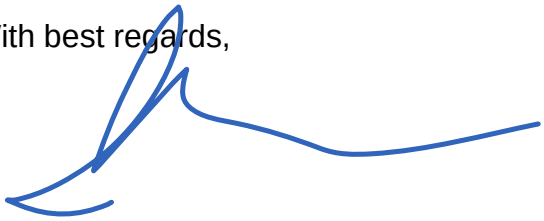
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 3.3)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-06 23.1_PDPRE 3.3 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 3.3) |
| Panel Date: | October 6, 2022 |
| Report Date: | October 11, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 3.3) meeting. The meeting did not have chair and was conducted via videoconference on October 6, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Three (3) applications were discussed and two (2) applications were not discussed
- Panelists: No (0) panel chair, and four (4) PDRC members
- 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.

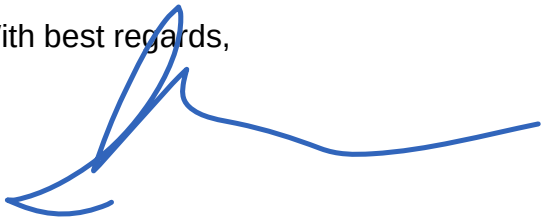
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.5)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-13 23.1_PDPRE 2.5 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 2.5) |
| Panel Date: | October 13, 2022 |
| Report Date: | October 19, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.5) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on October 13, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and four (4) applications were not discussed
- Panelists: One (1) panel chair, and three (3) PDRC members
- 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 two (2) Conflicts of Interest (COIs) identified prior to the meeting, and one potential COI identified during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

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

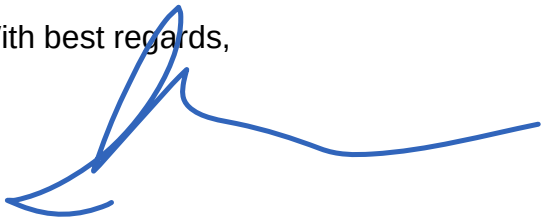
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE-3.6)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-20 23.1_PDPRE-3.6 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE-3.6) |
| Panel Date: | October 20, 2022 |
| Report Date: | October 25, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE-3.6) meeting. The meeting was moderated by Allison Milutinovich and was conducted via videoconference on October 20, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed, and four (4) applications were not discussed
- Panelists: One (1) PDRC Chair/Ad Hoc Reviewer, one (1) PDRC Vice Chair/Ad Hoc Reviewer, three (3) PDRC Members, and one (1) PDRC Member/Ad Hoc 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 was one (1) Conflict 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

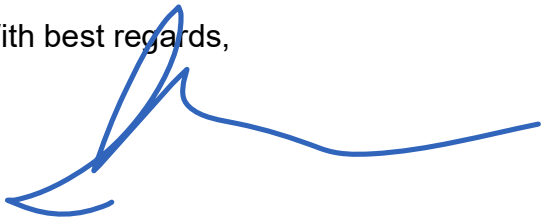
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Preliminary Panel-2.8
# (23.1_PDPRE 2.8)
# Observation Report

| | |
|---|---|
| Report No. | 2022-11-01 23.1_PDPRE 2.8 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Preliminary Panel-2.8 (23.1 _PDPRE 2.8) |
| Panel Date: | November 1, 2022 |
| Report Date: | November 4, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Preliminary Panel-2.8 (23.1_PDPRE 2.8) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on November 1, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers/PDRC members
- 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. The COI was excluded from discussions concerning the application for which there was a conflict.

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

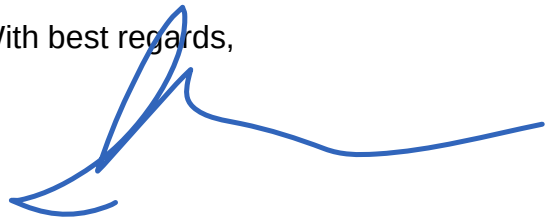
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Preliminary Panel 2.11
# (23.1_PDPRE 2.11)
# Observation Report

| | |
|---|---|
| Report No. | 2022-11-30 23.1_PDPRE 2.11 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Preliminary Panel 2.11 (23.1 _PDPRE 2.11) |
| Panel Date: | November 30, 2022 |
| Report Date: | December 6, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Preliminary Panel 2.11 (23.1_PDPRE 2.11) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on November 30, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair, 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: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

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

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

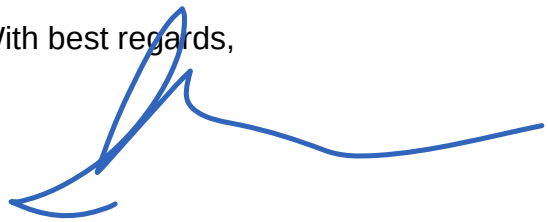
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-1
# (23.1_PDR_PDP1)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-12 23.1_PDR_PDP1 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-1 (23.1 _PDR_PDP1) |
| Panel Date: | December 12, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-1 (23.1_PDR_PDP1) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on December 12, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

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

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

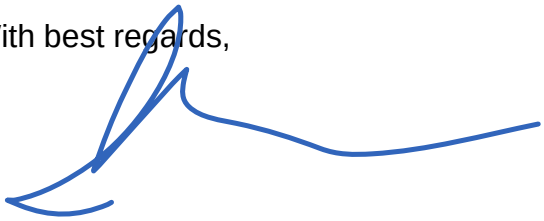
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-2
# (23.1_PDR_PDP2)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-12 23.1_PDR_PDP2 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-2 (23.1 _PDR_PDP2) |
| Panel Date: | December 12, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-2 (23.1_PDR_PDP2) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on December 12, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- 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.

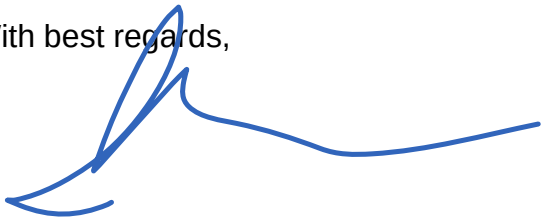
## *CONCLUSION*

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

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

# Re Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-3 (23.1_PDR_PDP3)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-13 23.1_PDR_PDP3 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-3 (23.1 _PDR_PDP3) |
| Panel Date: | December 13, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-3 (23.1_PDR_PDP3) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on December 13, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

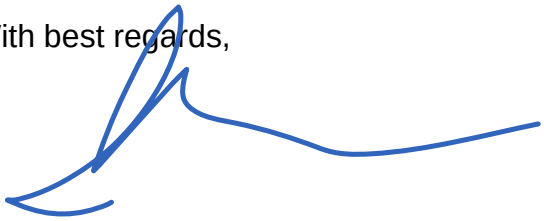
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-4
# (23.1_PDR_PDP4)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-13 23.1_PDR_PDP4 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-4 (23.1 _PDR_PDP4) |
| Panel Date: | December 13, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-4 (23.1_PDR_PDP4) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on December 13, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- 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.

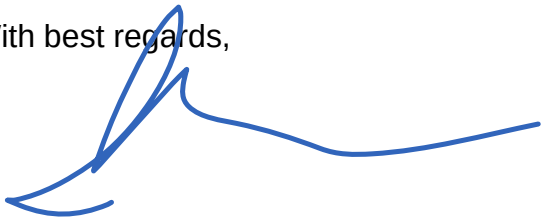
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-5
# (23.1_PDR_PDP5)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-14 23.1_PDR_PDP5 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-5 (23.1 _PDR_PDP5) |
| Panel Date: | December 14, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-5 (23.1_PDR_PDP5) meeting. The meeting was chaired by Bo Saxberg and conducted via videoconference on December 14, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

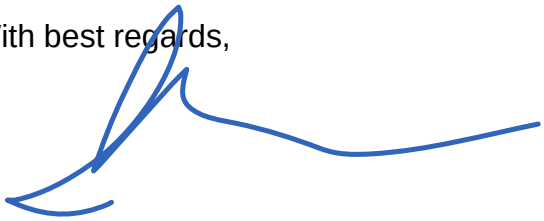
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-6
# (23.1_PDR_PDP6)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-14 23.1_PDR_PDP6 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-6 (23.1 _PDR_PDP6) |
| Panel Date: | December 14, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-6 (23.1_PDR_PDP6) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on December 14, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: 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.

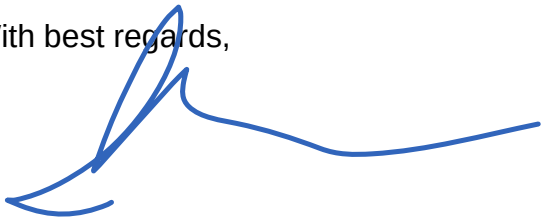
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-7
# (23.1_PDR_PDP7)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-15 23.1_PDR_PDP7 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-7 (23.1 _PDR_PDP7) |
| Panel Date: | December 15, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-7 (23.1_PDR_PDP7) meeting. The meeting was chaired by Alan West and conducted via videoconference on December 15, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

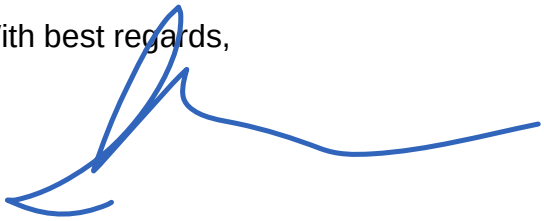
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-8
# (23.1_PDR_PDP8)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-15 23.1_PDR_PDP8 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-8 (23.1 _PDR_PDP8) |
| Panel Date: | December 15, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-8 (23.1_PDR_PDP8) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on December 15, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

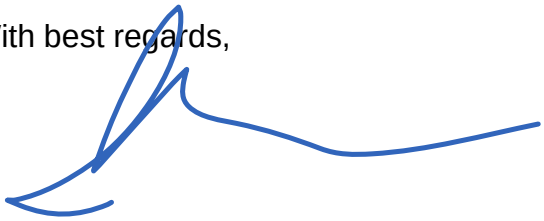
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-9
# (23.1_PDR_PDP9)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-16 23.1_PDR_PDP9 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-9 (23.1 _PDR_PDP9) |
| Panel Date: | December 16, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-9 (23.1_PDR_PDP9) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on December 16, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed
- 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

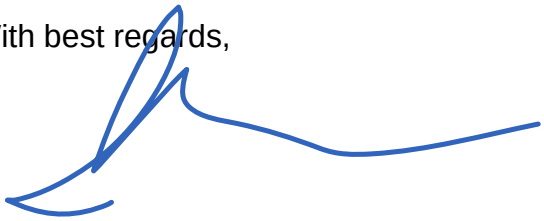
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-10
# (23.1_PDR_PDP10)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-16 23.1_PDR_PDP10 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-10 (23.1 _PDR_PDP10) |
| Panel Date: | December 16, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-10 (23.1_PDR_PDP10) meeting. The meeting was chaired by John McKew and conducted via videoconference on December 16, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

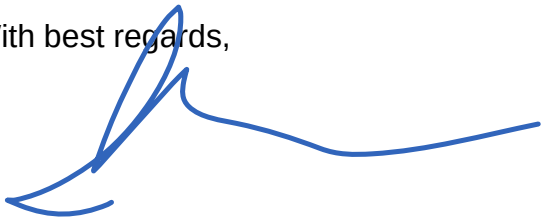
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Prelimenary Panel-1.16
# (23.1_PDPRE 1.16)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-12 23.1_PDPRE 1.16 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Prelimenary Panel-1.16 (23.1 _PDPRE 1.16) |
| Panel Date: | January 12, 2023 |
| Report Date: | January 18, 2023 |

## *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 23.1 Product Development Prelimenary Panel-1.16 (23.1_PDPRE 1.16) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on January 12, 2023.

## *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: Three (3) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel vice chair, 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: 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.

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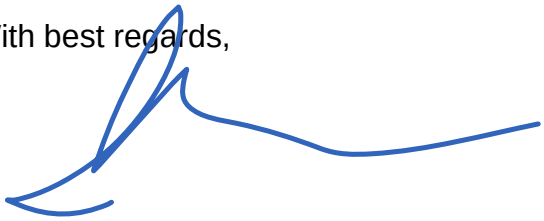
With best regards,



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)
# 23.1 Product Development Panel-1 Due Diligence (23.1_PDP-1 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-13 23.1_PDP-1 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-1 Due Diligence (23.1 _PDP-1 DD) |
| Panel Date: | January 13, 2023 |
| Report Date: | January 18, 2023 |

## 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 23.1 Product Development Panel-1 Due Diligence (23.1_PDP-1 DD) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on January 13, 2023.

## 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: 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 (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.

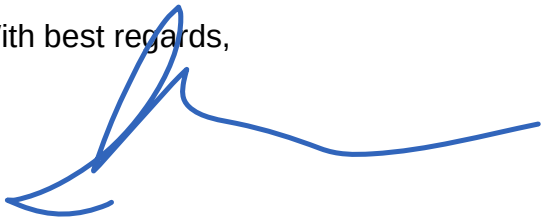
## *CONCLUSION*

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)
# 23.1 Product Development Panel-9 Due Diligence (23.1_PDP-9 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-13 23.1_PDP-9 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-9 Due Diligence (23.1 _PDP-9 DD) |
| Panel Date: | January 13, 2023 |
| Report Date: | January 18, 2023 |

## *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 23.1 Product Development Panel-9 Due Diligence (23.1_PDP-9 DD) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on January 13, 2023.

## *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
- Due Diligence Consultant Evaluators: Two (2)

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.

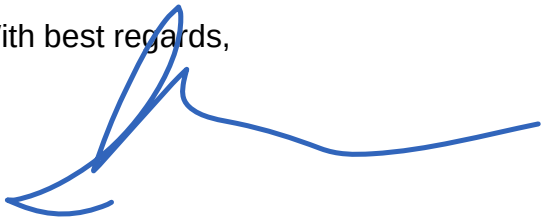
## *CONCLUSION*

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)
# 23.1 Product Development Panel-2 Due Diligence (23.1_PDP-2 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-18 23.1_PDP-2 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-2 Due Diligence (23.1 _PDP-2 DD) |
| Panel Date: | January 18, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-2 Due Diligence (23.1_PDP-2 DD) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on January 18, 2023.

## 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: 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.

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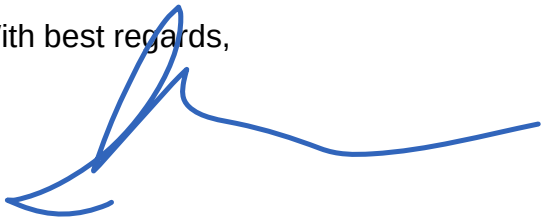
With best regards,



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)
# 23.1 Product Development Panel-8 Due Diligence (23.1_PDP-8 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-18 23.1_PDP-8 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-8 Due Diligence (23.1 _PDP-8 DD) |
| Panel Date: | January 18, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-8 Due Diligence (23.1_PDP-8 DD) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on January 18, 2023.

## 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: 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.

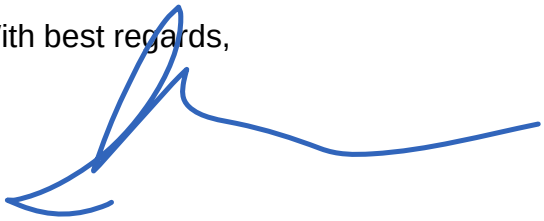
## *CONCLUSION*

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)
# 23.1 Product Development Panel-5 Due Diligence (23.1_PDP-5 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-19 23.1_PDP-5 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-5 Due Diligence (23.1 _PDP-5 DD) |
| Panel Date: | January 19, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-5 Due Diligence (23.1_PDP-5 DD) meeting. The meeting was chaired by Bo Saxberg and conducted via videoconference on January 19, 2023.

## 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, eight (8) 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

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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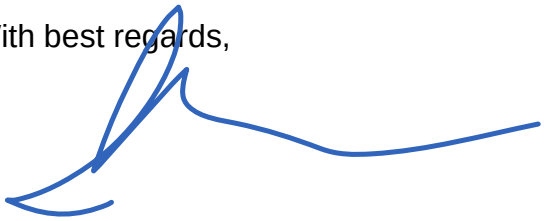
With best regards,



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)
# 23.1 Product Development Panel-3 Due Diligence (23.1_PDP-3 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-20 23.1_PDP-3 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-3 Due Diligence (23.1 _PDP-3 DD) |
| Panel Date: | January 20, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-3 Due Diligence (23.1_PDP-3 DD) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on January 20, 2023.

## 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 eight (8) 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.

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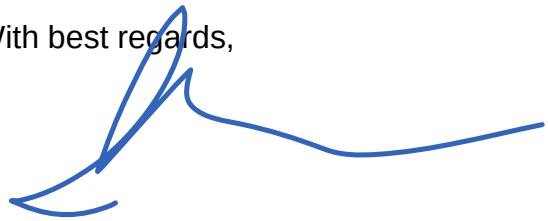
With best regards,



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)
# 23.1 Product Development Research - Product Development Review Council Meeting (23.1_PDR-PDRC)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-23 23.1_PDR-PDRC |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research - Product Development Review Council Meeting (23.1 _PDR-PDRC) |
| Panel Date: | January 23, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Research - Product Development Review Council Meeting (23.1_PDR-PDRC) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on January 23, 2023.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, one (1) panel vice-chair and ten (10) 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The COIs did not participate in discussions concerning applications for which there was a conflict.

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

## *CONCLUSION*

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

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

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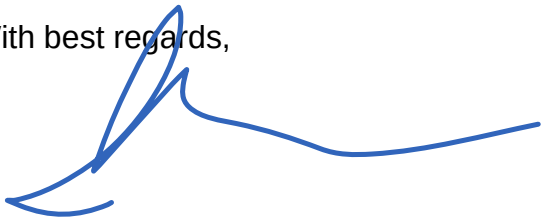
With best regards,



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 23.1

Awards Announced at the May 17, 2023, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 23.1 include: *SEED Awards for Product Development Research; Texas New Technologies Company Awards for Product Development Research; Texas Therapeutics Company Awards for Product Development Research* and *Texas Diagnostic and Devices Company Awards for Product Development Research.*

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:** | | | |
| DP230062 | Lewis, Lionel | 7 Hills Pharma LLC | Jones, Elaine |
| DP230066 | Scott, Brenton | Pulmotect, Inc | Geltosky, Jack |
| DP230076 | Stocks, Clifford | OncoResponse | Swiderek, Kristine |
| **Applications not considered by the PIC or Oversight Committee:** | | | |
| DP230031 (preliminary application) | Marija Plodinec | ARTIDIS, Inc | Weinstein, Steve |
| DP230045 (preliminary application) | Carole Spangler Vaughn | Eisana LLC | Swiderek, Kristine |
| DP230015 (preliminary application) | Jason Bock | Resilience Texas LLC dba CTMC | Shoemaker, David |
| DP230093 (preliminary application) | David Arthur | Salarius Pharmaceuticals, Inc. | Jones, Elaine |
| DP230103 | Paola Alvarado | Serene, LLC | Cosan, Roy |

| Application ID | Principal Investigator | Organization | Conflict Noted by Reviewer |
|---|---|---|---|
| (preliminary application) | | | |
| DP230063 (preliminary application) | Mauro Ferrari | BrYet US, Inc. | Canetta, Renzo |

# T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER |
| **SUBJECT:** | T.A.C. § 702.19 WAIVER |
| **DATE:** | FEBRUARY 1, 2023 |

## 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 six companies that the Product Development Review Council (PDRC) has recommended for grant awards. Doing so 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.

The total budget request for the proposed slate of six companies exceeds the remaining funds allocated for FY 2023 product development program awards. Approving this waiver allows Dr. Smith to negotiate proposed budgets and related goals and objectives with the six companies recommended by the PDRC for product development awards prior to final approval by the Oversight Committee. At its February 1 meeting, the Program Integration Committee (PIC) approved deferring final PIC action on the PDRC's recommendations until the May Oversight Committee meeting. The additional time and this waiver serve our goal of reducing the budget requests by an amount such that CPRIT may fund most or all companies recommended by the PDRC. Granting this 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 2023 product development awards.

# High Level Summary of Due Diligence

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- OmniNano Pharmaceuticals LLC for $2,711,437.

The contract contingencies recommended by the PDRC for this award have been satisfied.

OmniNano Pharmaceuticals LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

OmniNano Pharmaceuticals LLC is a Missouri City-based company which is developing a platform using polymeric micellar nanocarrier to codeliver distinctly different drugs to tumors which thereby increases therapeutic concentrations of individual drugs in a simultaneous manner.

Pancreatic ductal adenocarcinoma (PDAC) has a 5-year survival rate of just 11.5% and an overall median survival time of <1 year with the current standard-of-care treatments. This proposal seeks to develop a polymeric micelle-based solution to PDAC based on a micellar co-formulation delivery platform for cyclopamine (CPA), a naturally-occurring compound capable of depleting cancer stem cells, and paclitaxel (PTX), a cytotoxic chemotherapeutic agent that eliminates proliferating cancer cells. In preclinical studies, the polymeric micelles containing both CPA and PTX, named ONP-001, significantly prolonged the median survival of transgenic KPC mice that harbor certain mutations. In a randomized study, ONP-001 increased median survival of mice by 8-fold compared to nab-paclitaxel and by 7-fold compared to gemcitabine. ONP-001 increased the area of benign pancreatic tissue by 270% and substantially reduced poorly differentiated or moderately differentiated tumor cells.2 The strong anti-PDAC efficacy was achieved with a minimal systemic toxicity. ONP-001 overcomes poor drug delivery of therapeutic agents by continuously remodeling tumor stroma to normalize tumor blood vessels and alleviate tumor hypoxia, which leads to increased ONP-001 delivery via a positive reinforcing feedback loop for delivery efficiency. The goals of the proposed project are to manufacture ONP-001 under current Good Manufacture Practice (cGMP) guidance, to conduct GLP-toxicity and toxicokinetic studies (rodents and non-rodents), and to prepare a robust IND (investigational new drug) package to be filed with the FDA.

**Select Reviewer Comments**

*ONP-01 is an innovative product with potential for effective treatment of PDAC.*

*The management team has experience in managing clinical research projects in nanomedicine, as well as on the development of novel drug-delivery systems for selective delivery of diagnostic and therapeutic agents. The team also includes an expert in pharmacokinetics (PK) and pharmacodynamics (PD) of drug formulations.*

*Strong preclinical data that demonstrate feasibility of clinical approach.*

TNTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Resilience Texas LLC dba CTMC for $9,100,000.

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

Resilience Texas LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Cell Therapy Manufacturing Center (CTMC) is a Houston-based joint venture between National Resilience Inc. and MD Anderson Cancer Center (MDACC) to accelerate cell therapy development. There has been a 10-fold increase in cancer cell therapy trials over the last decade. CTMC focuses on three areas to benefit patients and technology by building capacity and differentiated capabilities for retroviral vector (RVV) manufacturing, tumor infiltrating lymphocyte (TIL) platform improvement, and CAR-T process development strategy.

Autologous cell therapies manufacturing process is fraught with bottlenecks that limit treatment access for many patients due to length of time and high production costs. CTMC's current scientific and structural advantages in autologous cell therapy includes a 60,000 SF facility adjacent to MDACC. The project will provide a vertically integrated approach to 1) accelerate novel therapies to the clinic (reduce time from research to clinical proof of concept) 2) provide a robust strategy to move products from clinical proof of concept to commercialization, and 3) drive down the long-term commercial cost of cellular therapy products.

There are few manufacturing centers that focus on retroviral vectors, and little to no development of downstream process development of the RVV. CTMC will utilize a two-pronged approach: optimized transient transfection to make RVV for a fast-to-clinic strategy as well as development of a robust clonal pools, selected clones, and downstream purification RVV process to support a

streamlined approach for later stage therapies which will provide a reduced overall development timeline.

TIL therapy is a proven and effective option in melanoma, and much of the development of successful manufacturing processes done by the scientific staff that moved from MDACC to CTMC. The project will utilize CTMC's prior expertise in TIL optimization to improve the second phase of the process through final formulation. These improvements will develop a robust and broadly applicable potency assay that is currently lacking in the field, which will open doors for exploration of novel engineering in the TIL field, expansion to additional cancer indications.

Autologous cellular therapies require dedicated equipment, highly trained operators, and individual manufacturing for each patient. CAR-T processes are typically developed solely with healthy donor blood products and standard/unoptimized cryopreservation methods. CTMC proposes to develop scale-down models, accessing and incorporating patient samples during development with quicker and less costly evaluation of automated steps, and by developing data-driven methods for freezing products based on cryopreservation strategies.

The proposal provides that CTMC establish a robust and flexible center for retroviral vector (RVV) manufacturing in Texas; Expand platform expertise by optimizing tumor infiltrating lymphocyte (TIL) manufacturing and provide a differentiated process development approach for CAR-T manufacturing.

**Select Reviewer Comments**

**"***Major strengths of the application include the objectives, which have identified bottle necks in RRV, CAR-T, and TIL manufacturing and propose innovative strategies to overcome them. The close partnership with MD Anderson and a regulatory staff, which allows for essentially 1-stop preclinical to clinical development of cell-based therapeutics, is highly innovative."*

**"***This is a very innovative concept and structure potentially addressing some of the challenges in the cell and gene therapy space … builds permanent jobs in Texas and adds to the needed biotech infrastructure to create a true biotech/oncology ecosystem."*

*"The development plan indicates an opportunity to further research and develop a technology that will save time to get treatment to patients."*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Alterum Therapeutics LLC for $11,721,150.

The contract contingencies recommended by the PDRC for this award have been satisfied.

Allterum Therapeutics LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Allterum Therapeutics LLC is a Houston-based preclinical company formed around research conducted at National Cancer Institute of a monoclonal antibody, 4A10, against CD127 as a treatment for acute lymphoblastic leukemia (ALL). CD127 is a subunit for both the interleukin-7 receptor (IL-7R) and the TSLP receptor, which are expressed on T-Cell ALL and pre-B Cell ALL, respectively. 4A10 binds CD127 and exerts its anticancer activity by a dual mechanism: inhibition of IL-7 signaling and cytotoxicity via ADCC mediated by its IgG1 Fc region. 4A10's anti-cancer activity in ALL has been demonstrated both in vitro and in vivo in multiple labs, including patient-derived xenograft (PDX) models.

There are about 7,000 cases of ALL in the U.S. each year with ~1,600 deaths. ~80% of ALL patients are children, making it the most common childhood cancer in the U.S. ~80% of ALL patients have pre-B cell ALL (B-ALL) and ~20% have T-cell ALL (T-ALL). ALL treatment is a relative success story in cancer. Both B-ALL and T-ALL patients receive a similar first-line regimen, to which ~85% respond. Several options exist for patients with B-ALL who progress after first-line therapy, but a third will still progress or be unable to tolerate available treatments. Patients with T-ALL who progress have an even poorer prognosis, with no approved targeted second-line options. Patients with relapsed or refractory (r/r) ALL have poor outcomes with a 15-35% five-year survival, and are the initial focus of our development.

4A10 is expected to be well tolerated and active even in relapsed disease, it would be attractive to patients who have failed or cannot tolerate other available therapies. The clinical goal of the project is to get a complete response without minimal residue disease making the patient eligible for a potentially curative stem cell transplant. The long-term goal is to expand the label to add 4A10 to standard first-line therapy to increase effectiveness and/or decrease toxicity.

A prior CPRIT Seed award supported scale up 4A10 manufacturing, conduct early toxicological studies, develop clinical protocol, and obtain pre-IND guidance from FDA. 4A10 has received orphan drug and pediatric rare disease designation in ALL. The proposal provides that Allterum will Manufacture of Drug Substance (DS) and Drug Product (DP) under GMP; Perform Pivotal GLP Toxicology Studies to support IND filing; Submit IND and IRB filings and initiate clinical trial site(s) for the Phase I/IIA Clinical Trial of 4A10 in Patients with relapsed/refractory Acute Lymphoblastic Leukemia (r/r ALL); and Conduct First-in-Human Phase I/IIA Clinical Trial for 4A10 in r/r ALL patients.

**Select Reviewer Comments**

*"There is an unmet need for treating recurring or resistant forms of ALL. This applicant is proposing the development of a product to provide benefit to these patients with a low-toxicity product … The applicant has had a pre-IND meeting with the FDA and has incorporated the FDA recommendations into their study design, ie, monotherapy for 28 days. Additionally, the applicant indicates that they have already received orphan drug and pediatric rare disease designation for 4A10 in ALL."*

*"This proposal is very Texas-centric, and the conduct of this work will further both CPRIT's goals and successes."*

*"Novel effective treatment options for relapsed/refractory ALL are needed, and the intended product that targets CD127 could satisfy an unmet need for treatment."*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- 7 Hills Pharma LLC for $13,439,001.

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

7 Hills Pharma LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

7 Hills Pharma LLC is a Houston-based company which is developing 7HP349 which is a first-in-class, oral, small molecule, positive allosteric modulator of integrins critical for immune surveillance (immune cell priming, trafficking and effector functions) that may increase the effectiveness of CPI, with a low risk of elevated immunotoxicities, in PD-1 resistant cancers.

7HP349 as systemic drug has been shown to have single-agent antitumor activity, is synergistic with PD-(L)1, aCTLA-4, and immunogenic doses of radiation with tumor-selective homing of antigen-specific T cells. The priming dose, schedule, and plasma exposures have been defined in multiple mouse tumor and infectious disease models. 7HP349 has been shown not to increase immunotoxicies.

In a Phase I healthy volunteer study, 7HP349 was orally bioavailable with a safety margin of >10x based on the optimal pharmacokinetic (PK) exposures with a minor positive food effect. The single dose and repeat dose PK were non-linear, and the T ½ of ~20h supported once-daily

dosing. 7HP349 doses of 100-300 mg will be dose escalated in combination with ipilimumab and nivolumab.

7 Hills has developed scalable, low-cost manufacturing processes and estimate ambient stability of 5 and 3 years for the 7HP349 Drug Substance (DS) and Product (DP). 16 kg of cGMP DS and 30,000 capsules of DP have been produced and will be ready for clinical use in 2Q2023.

US FDA has granted 7HP349 Orphan Drug designation for treatment of malignant melanoma stages IIB to IV and Fast Track designation for 7HP349 in combination with a CTLA-4 inhibitor for the treatment of patients with unresectable or metastatic *MM* following prior PD-1 inhibitor treatment.

The proposed project aims to establish target-centric patient selection biomarker; manufacture and release of cGMP 7HP349 Drug Product(s) (DP), and complete registrational ICH stability programs; complete the 7HP111, Phase Ib/IIa clinical trial to determine the safety and efficacy of oral 7HP349 in combination with ipilimumab followed by nivolumab in patients with locally advanced or metastatic malignancies (melanoma, HNSCC, NSCLC) resistant to or relapsing after PD-1 inhibitor therapy.

**Select Reviewer Comments**

*"The application states that over 40% of patients with metastatic melanoma are resistant to checkpoint inhibitor therapies. An oral medication that can increase the effectiveness of current immunotherapies without an increase in toxicities would be of benefit to such patients."*

*"7 Hills Pharma is pursuing an unmet medical need with a novel mechanism targeting resistant metastatic melanoma patients with aPD-1 resistance by enhancing ICI effectiveness with 7HP349, a first-in-class, oral, small-molecule, positive allosteric modulator of integrins critical for immune cell priming, T cell trafficking and effector functions."*

*"7 Hills Pharma has presented impressive in vivo pharmacodynamic effects with 7HP349 including significant inhibition of tumor growth and increased response rate in combination with aPD-1 and aCTLA-4 immune checkpoint inhibitors and effected an increase in the recruitment of CD4 and CD8 T cells into the tumor. "*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Pulmotect Inc. for $8,851,165.

The contract contingencies recommended by the PDRC for this award have been satisfied.

Pulmotect Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Pulmotect, Inc. is a Houston-based company which is developing an immunomodulatory technology to treat and prevent respiratory infections in immunocompromised cancer patients to improve cancer patient outcomes. PUL-042 inhalation solution contains two active ingredients, which act synergistically on Toll-like receptors to stimulate pulmonary epithelial innate immunity and protect against a wide range of pathogens.

Respiratory infections are caused by a variety of pathogenic organisms including viruses, bacteria, and fungi. Cancer patients are highly susceptible to respiratory infection and potentially lethal pneumonia due to suppressed *adaptive* immunity. Pneumonia is second only to the underlying cancer in causing death in cancer patients.

Cancer patients still have intact respiratory epithelium that can respond to stimuli. By stimulating these *innate epithelial immune responses* in the lung and enhancing the ability to fight off invading pathogens, patients can be protected from pulmonary infections, thereby reducing morbidity and mortality. PUL-042, is administered by inhalation and activates the lung epithelial innate defense mechanisms through stimulation of specific lung epithelial Toll-like receptors providing broad protection against invading pathogens. Extensive *in vitro* and *in vivo* preclinical experiments and toxicology studies have demonstrated safety and broad protection against pathogens. PUL-042 has clinical evidence of anti-viral activity against the SARS-CoV-2 virus in a Phase 2 clinical trial. Data in more than 200 PUL-042 treated subjects demonstrate safety and clinical proof of concept thereby increasing the probability of successful development.

Pulmotect proposes to Initiate a Phase 2 Clinical Trial; Complete Patient Enrollment and Complete Final Study Report:

**Select Reviewer Comments**

*Pulmonary infection (pneumonia) among immunocompromised patients is a well established area of unmet clinical need, accounting for the proximate cause of mortality among many hospitalized patients. A "pathogen" agnostic therapeutic modality would have widespread applications.*

*Given the high mortality from pneumonia in immunocompromised cancer patients, the challenges of rapid diagnosis and treatment of one or multiple lung infections and the promise of prophylaxis and/or treatment of viral, bacterial or fungal infections by stimulation of innate immunity in the lung, there is tremendous unmet need and potential for PUL-042.*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- OncoResponse for $13,259,174.

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

OncoResponse Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

OncoResponse is a Seattle-based company which is developing OR502 which is a humanized monoclonal antibody for treatment of advanced human malignancies. The target of OR502 is the leukocyte immunoglobulin-like receptor-2/immunoglobulinlike transcript-4 (LILRB2/ILT4) protein which is expressed on the surface of certain immune cells known to play a role in immune response to cancer. OR502 disrupts immuoinhibitory actions of LILRB2, leading to immune stimulation and potentiation of anti-cancer responses.

OR502 is a humanized monoclonal antibody that binds with high affinity and specificity to an epitope on LILRB2 distinct from all other clinical candidates, including MK-4830. OR502 demonstrates specific binding to myeloid cells, no binding to a panel of other immune cells, and potently blocks the interaction of LILRB2 with HLA-G and other HLA-class I molecules. In pre-clinical studies, OR502 demonstrates superior characteristics versus competitors. OR502 outperforms MK-4830 in restoring CD8+ T-cell proliferation, interferon gamma and perforin secretion in M2c/CD8+ T cell coculture assay and rescues interferon gamma production in M2c/Exhausted CD8+ T cell coculture assays. OR502 has 2-pronged functionality, as it reduces the immunosuppressive phenotype of existing tumor associate macrophages (TAMs) and prevents development of new immunosuppressive TAMs.

OncoResponse is developing an OR502-expressing cell line, cell culture process, purification process, analytical methods, and formulation and completed a manufacturability assessment which showing excellent characteristics.

OR502 will be developed for the treatment of solid tumors. The development plan will first determine the safe dose of OR502 in subjects with advanced solid malignancies for which no standard therapies exist, and then evaluate additional safety and potential activity in tumor-specific expansion cohorts. The Phase 1 study will use an efficient dose-escalation design to rapidly determine a safe and potentially efficacious dose and schedule. Concurrent with

monotherapy dose escalation, combination cohorts with an anti-PD-(L)1 will be enrolled to evaluate safety of OR502 in combination.

OncoResponse's proposal provides for completing all IND-enabling studies for OR502 and file NDA with FDA; initiating Phase 1A clinical trials to assess safety and dose level; completing Phase 1A trials and establish RP2D (monotherapy and in combination with anti-PD-1; initiating dose-expansion for 2 indications (monotherapy and in combination); initiating monotherapy biology cohort and conduct additional biomarker analysis and assessing initial ORR for initial patients in expansion and biology cohorts

**Select Reviewer Comments**

*The management team is very strong and experienced, including the CEO who has many years of experience in raising venture capital and mergers and acquisitions. The CMO is a medical oncologist who trained at NIH and has many years of experience in the pharmaceutical industry. The CSO is experienced in biomarker development and generating preclinical data.*

*This is a validated target with potential for addressing important unmet/emerging needs in a variety of cancers.*

*This is a very strong resubmission of an application focused on addressing the unmet need in ICI response.*

# De-Identified Overall Evaluation Scores

# SEED Awards for Product Development Research

Product Development Research Cycle 23.1

*Full Application Review*

| Application ID | Meeting Overall Score |
|---|---|
| DP230064* | 3.3 |

* Recommended for award.

# SEED Awards for Product Development Research

Product Development Research Cycle 23.1

*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 |
|---|---|
| Aa | 4.0 |
| Ab | 4.3 |
| Ac | 4.3 |
| Ad | 4.5 |
| Ae | 4.7 |
| Af | 5.0 |
| Ag | 5.3 |
| Ah | 5.3 |
| Ai | 6.0 |
| Aj | 6.3 |

* Recommended for full application review.

# Final Overall Evaluation Scores and Rank Order Scores

January 30, 2023

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

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

Dr. Patel and Mr. Roberts,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 23.1 grant award cycle. The PDRC convened on January 23, 2023 and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Resilience Texas LLC dba CTMC, Allterum Therapeutics, LLC, 7 Hills Pharma, LLC, Pulmotect, Inc., OmniNano Pharmaceuticals LLC, OncoResponse. The attached table reflects the ranked award recommendation for the six (6) grant applications that CPRIT would like deferred to the May 2023 Oversight Committee meeting.

The PDRC did not make any changes to timelines or budgets for the six (6) projects recommended for funding. However, four (4) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP230071, DP230076, and DP230079 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP230066 related to clinical data and statistical analysis. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

# FY23.1 Product Development Review Council Recommendations

| Ranking | ID | Mechanism | Type | PI Last Name | Application Title | Organization | Score from Due Diligence | Budget |
|---|---|---|---|---|---|---|---|---|
| 1 | DP230079 | TNTC | New | Bock, J | Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value-Added Biotech Partnerships | Resilience Texas LLC dba CTMC | 2.3 | $12,000,000 |
| 2 | DP230062 | TTC | New | Lewis, L | 7HP349, a Small Molecule, Oral Integrin Activator to Treat Patients With anti-PD-1 Resistant Melanoma | 7 Hills Pharma LLC | 2.6 | $18,679,381 |
| 3 | DP230064 | SEED Therapeutics | New | Ma, G | IND-Enabling Studies of ONP-001: A Nano-Codelivery Formulation with Two Drugs of Distinct Mechanisms of Action for Treating Pancreatic Ductal Adenocarcinoma | OmniNano Pharmaceuticals LLC | 3.3 | $2,999,858 |
| 4 | DP230076 | TTC | New | Stocks, C | OncoResponse OR502 anti-LILRB2 monoclonal antibody Phase 1-2 clinical study | OncoResponse | 3.6 | $19,326,953 |
| 5 | DP230066 | TTC | Resubmission | Scott, B | Improving Cancer Patient Outcomes by Activating Lung Innate Immunity | Pulmotect, Inc. | 3.3 | $12,445,092 |
| 6 | DP230071 | TTC | Resubmission | Varadhachary, A | Clinical development of a novel CD127 antibody for treating patients with relapsed/refractory Acute Lymphoblastic Leukemia (ALL) | Allterum Therapeutics, LLC | 2.6 | $17,005,376 |

Cancer Prevention & Research
Institute of Texas

# CEO Affidavit
# Supporting Information

**Product Development Research**
**FY 2023—Cycle 1**
***Texas New Technologies Company Awards for Product Development Research***

# Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS
# RFA 23.1-TNTC

## Texas New Technologies Company Awards for Product Development Research

**Please also refer to the Instructions for Applicants document, which CPRIT will post August 24, 2022**

**Preliminary Application Receipt Opening Date:** August 24, 2022

**Full Application Receipt Closing Date:** May 1, 2023

**FY 2023**

Fiscal Year Award Period

September 1, 2022-August 31, 2023

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# RFA VERSION HISTORY

Rev 8/24/2022 RFA release

Rev 10/11/2022 Section 6.4 – Preliminary and Full Application Submission Deadlines

- Edited to clarify how many full applications will be reviewed in the first full application review cycle

Section 8.3 – Goals and Objectives (G&Os)

- Edited to clarify that G&Os in the full application should not vary significantly from the aims presented in the preliminary application

Section 8.12 – Budget

- Edited to clarify that the total budget included in the full application must not vary significantly from the anticipated budget request included in the applicant's preliminary application

# 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 at any time, which a panel of experts will review within 3 to 5 weeks of receiving the submission. If the preliminary application demonstrates sufficient scientific merit and appears to be an appropriate fit for CPRIT's portfolio, CPRIT will invite the company 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. For planning purposes, CPRIT's review schedule links panel presentation dates and final award decisions to the 3 application submission deadlines offered per CPRIT's fiscal year (September 1-August 31).

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.

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 Awards to contribute the company's own funds toward the project contemporaneous 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 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." 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 FY 2023 are as follows:

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

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 New Technologies Company Awards

Funding available through this RFA supports the ongoing research and development of new and emerging technologies for the detection, diagnosis, prognosis, monitoring, or treatment of cancer. CPRIT created this RFA to fund new and emerging technology projects that do not easily fit into any of the 4 other CPRIT Product Development Research RFAs. 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.

With appropriate justification, companies may use CPRIT funds to support studies that establish preclinical proof of concept, 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 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

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 one 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. Resubmission Policy

For the FY 2023 review cycle, CPRIT will consider the company's first preliminary application, and subsequent full application if CPRIT invites the company to submit a full application, as a new application, even if the company previously applied prior to August 22, 2022.

A company may resubmit a preliminary application 1 time (for a total of 2 submissions) during the FY 2023 review cycle. 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. 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 2-step process to review company projects proposed for funding. An integrated panel of individuals with expertise in biotechnology and basic/translational/clinical cancer research as well as regulatory approval processes will review all applications. Cancer patient advocates also participate in the review of full applications.

All 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. 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.

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.

The company may submit a preliminary application at any 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. The review process ends after preliminary review for those applicants not invited to submit a full application.

Absent unusual circumstances, CPRIT will notify the applicant of the outcome of the preliminary review within 3 to 5 weeks.

## 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 also convenes virtually for the applicant to present the application in person and respond to reviewers' questions.

### 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 aspects, manufacturability, and market assessments. The applicant should be prepared to provide CPRIT with any correspondence that the company has conducted with regulatory agencies (eg, the FDA).

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 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 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 support expectations of clinical impact
- Proposed Integrated Product Development Plan (IPDP)
- 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 one 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.** Applicants must create a CARS user account to generate and submit the application. The *Instructions for Applicants* associated with this RFA provide information about establishing a user account.

## 6.2. Invitations to Submit Full Applications Valid Only for the FY 2023 Review Process

The invitation to submit a full application is valid only for the FY 2023 review cycle. This means that a company must submit its full application no later than May 1, 2023, for CPRIT to consider the project for FY 2023 award funding. An applicant invited to submit a full application in FY 2023 but does not do so must restart the review process in a future cycle by resubmitting the preliminary application. However, the resubmission will not count against the limit in CPRIT's resubmission policy.

## 6.3. CPRIT May Elect to Close the FY 2023 Review Cycle Early If Funds Are Unavailable

Applicants should be cognizant that CPRIT has limited funds available to fund Product Development Awards (approximately $70 million for the FY 2023 review cycle). CPRIT may cease accepting applications for the FY 2023 review cycle and/or defer applications to the FY 2024 review cycle if the amount approved for FY 2023 Product Development Awards exceeds $70 million prior to the close of the FY 2023 review cycle.

## 6.4. Preliminary and Full Application Submission Deadlines; Other Key Dates

Preliminary Applications: An applicant may submit a preliminary application via CARS at any time on or after August 22, 2022.

Full Applications: CPRIT will convene review panels up to 3 times during the FY 2023 review process for in-person presentations of full applications. Invited applicants may elect to submit the full application by one of the deadlines listed below, and the next available review panel will consider the application. Key dates for the FY 2023 review cycles:

| **FY 2023 Review Cycle 1** | |
|---|---|
| Full Application Deadline | November 1, 2022; 4:00 PM central time |
| In-Person Presentation | Week of December 12, 2022 |
| Due Diligence | December 2022-January 2023 |
| Oversight Committee Meeting | February 15, 2023 |

| **FY 2023 Review Cycle 2** | |
|---|---|
| Full Application Deadline | February 1, 2023; 4:00 PM central time |
| In-Person Presentation | Week of March 13, 2023 |
| Due Diligence | March-April 2023 |
| Oversight Committee Meeting | May 17, 2023 |

| **FY 2023 Review Cycle 3** | |
|---|---|
| Full Application Deadline | May 1, 2023; 4:00 PM central time |
| In-Person Presentation | Week of June 12, 2023 |
| Due Diligence | June-July 2023 |
| Oversight Committee Meeting | August 16, 2023 |

CPRIT will endeavor to assign all applications received by the review cycle deadline to the next available in-person presentation panel. However, if the number of applications received by the deadline exceeds the review panel's ability to provide a thorough, fair review, CPRIT will use its discretion to assign the application to a future review panel. Due to schedule constraints, CPRIT has the capacity to review no more than 10 full applications in the first review cycle (full application deadline November 1, 2022). If the number of full applications submitted by the November 1 deadline exceeds 10, then CPRIT will review the first 10 full applications submitted

in CARS as reflected by the date/time of the submission. For those full applications submitted in the first review cycle but not reviewed, CPRIT will defer the review to the second review cycle (full application deadline February 1, 2023).

## 6.5. Submission Deadline Extensions

In-person panel presentation schedules are set in advance and do not accommodate receipt of a 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 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 a minimum of 5 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.

## 6.6. 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 make the payment by check or money order payable to "Cancer Prevention and Research Institute of Texas." Indicate the application ID and the name of the submitter on the check. CPRIT will not accept electronic and 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. 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 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. Brief description of asset/technology
b. Unmet medical need/initial target indication(s)/patient populations: tumor type(s), stage, extent of prior standard of care (SOC) therapy
c. Preclinical proof of concept

d. Product validation
e. Safety characterization to date
f. Manufacturing development status
g. Regulatory status and plan (eg, agency interactions to date and planned, likely regulatory paths)
h. High-level overview of work to be done during the grant, including key milestones and budget estimates by year
i. Competition
j. Management team

### 7.2. 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.

### 7.3. 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.

## 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.

### 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), particularly 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 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 one 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 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 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. Brief description of asset/technology
b. Unmet medical need/initial target indication(s)/patient populations: tumor type(s), stage, extent of prior SOC therapy
c. Preclinical proof of concept
d. Product validation
e. Safety characterization to date
f. Manufacturing development status

g. Regulatory status and plan (eg, agency interactions to date and planned, likely regulatory paths)
h. High-level overview of work to done during the grant, including key milestones and budget estimates by year
i. Competition
j. Management team

## 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 1 page)

If the applicant submitted a preliminary or full application to CPRIT prior to August 2022 or if the applicant is resubmitting a preliminary or full application already submitted in the FY 2023 review cycle, upload a summary of the 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 application 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 chemistry, manufacturing, and controls plan to ensure that the company has sufficient investigational product available for studies
d. The regulatory activities and timelines associated with each plan

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 one 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.

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:

a. Type of product or service
b. Intended uses: therapeutic treatment decision, detection, diagnosis, prognosis, prediction, monitoring, manufacturing
c. Unmet need

d. Stage of development of the product: proof-of-concept, prototype, validation, clinical
e. Product validation: Describe nonclinical and clinical trial data and designs intended to demonstrate the effects of the product or process
f. Manufacturing of prototype, scaleup, commercial scale
g. Type and methods for quality measurement planned in QA/QC
h. Assessment of quality vs cost (cost of goods [COGs] below) at expected commercial scale
i. Completed and planned clinical studies for marketing approval, if applicable
j. Regulatory pathway: 510(k), PMA
k. IP
l. Licensing agreements
m. Competitive analysis
n. 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 product 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.

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 vs 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 CRO input into budget preparation.

### 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.
c. The possibility of a Priority Review by the FDA.
d. Whether to pursue an accelerated approval pathway.

NOTE: Applicants must separately upload into CARS as a standalone document meeting minutes of all FDA meetings related to the product that is the subject of the CPRIT application. This is a continuing obligation that extends over the course of the application review process. If the applicant receives meeting minutes after submitting the application but before CPRIT has made a final decision on the application, the application should contact the CPRIT Helpdesk (see section 10.1) for assistance on filing the additional information.

### 8.8.6. 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)/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 cost of goods, including the program management of anticipated contractors and the sourcing of raw materials, reagents, supplies, and instruments.

### 8.9. Business Plan (maximum 11 pages)

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 provides 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)

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.

### 8.9.6. Commercial Strategy (maximum 1 page)

a. Provide an overview of the company's financial projections and how the company plans to generate a return on this investment.
b. Describe how the company plans to bring the product to market. Information on targeted physicians, sales channels, etc, is helpful.
c. Alternatively, if the company's plan includes acquisition by a larger medical device/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, 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. 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.

### 8.9.10. 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. 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" 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) 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 FY 2023 annual salary is $200,000. An individual may request salary proportional to the percent effort up to a maximum of $200,000. 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 $200,000. CPRIT may revise the FY 2023 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 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 $1 of funds under the company's control for every $2 of CPRIT grant award funds.
- A company approved for one or more CPRIT product development grants that together total a commitment of more than $20 million must increase their matching fund obligation to $1 for every $1 contributed by CPRIT.

  The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under CPRIT's matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.
- A company approved for one or more CPRIT product development grants that together total a commitment of more than $30 million must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

# 10. CONTACT INFORMATION

## 10.1. Helpdesk

The Helpdesk will answer queries submitted via email within one 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.

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|---|---|
| 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: | Help@CPRITGrants.org |
| 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 knowhow?
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; 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)
# 23.1 Product Development Research Preliminary Application Review 1.1 (23.1 _PDPRE 23.1 - 1.1)
# Observation Report

| | |
|---|---|
| Report No. | 2022-09-22 23.1_PDPRE 23.1 - 1.1 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review 1.1 (23.1 _PDPRE 23.1 - 1.1) |
| Panel Date: | September 22, 2022 |
| Report Date: | September 28, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Preliminary Application Review 1.1 (23.1_PDPRE 23.1 - 1.1) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on September 22, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and three (3) PDRC members
- 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.

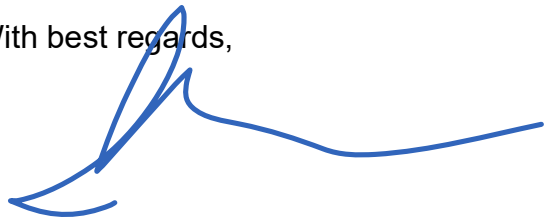
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.2)
# Observation Report

| | |
|---|---|
| Report No. | 2022-09-26 23.1_PDPRE 2.2 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 2.2) |
| Panel Date: | September 26, 2022 |
| Report Date: | September 28, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.2) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on September 26, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and one (1) application was not discussed
- Panelists: One (1) panel chair, three (3) PDRC members
- 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 (COIs) identified prior to and/or during the meeting.

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

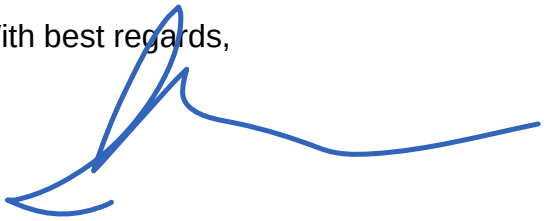
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 1.4)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-06 23.1_PDPRE 1.4 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 1.4) |
| Panel Date: | October 6, 2022 |
| Report Date: | October 11, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 1.4) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on October 6, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed
- Panelists: One (1) panel chair, and three (3) PDRC members
- 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.

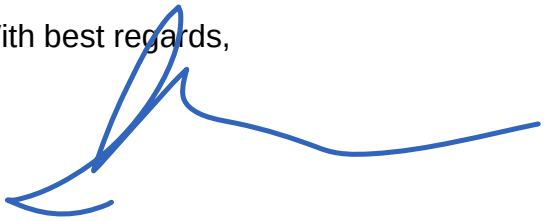
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 3.3)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-06 23.1_PDPRE 3.3 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 3.3) |
| Panel Date: | October 6, 2022 |
| Report Date: | October 11, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 3.3) meeting. The meeting did not have chair and was conducted via videoconference on October 6, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Three (3) applications were discussed and two (2) applications were not discussed
- Panelists: No (0) panel chair, and four (4) PDRC members
- 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.

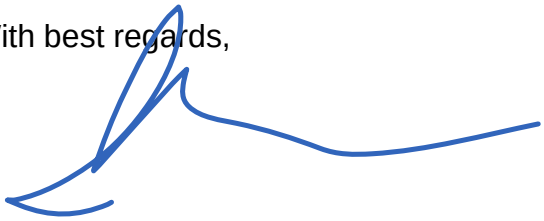
## *CONCLUSION*

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

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Cameron Eckel, Attorney

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.5)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-13 23.1_PDPRE 2.5 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 2.5) |
| Panel Date: | October 13, 2022 |
| Report Date: | October 19, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.5) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on October 13, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and four (4) applications were not discussed
- Panelists: One (1) panel chair, and three (3) PDRC members
- 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 two (2) Conflicts of Interest (COIs) identified prior to the meeting, and one potential COI identified during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

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

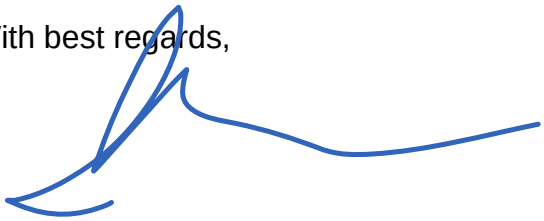
## *CONCLUSION*

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

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

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

With best regards,



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Senior Partner
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Cameron Eckel, Attorney

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE-3.6)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-20 23.1_PDPRE-3.6 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE-3.6) |
| Panel Date: | October 20, 2022 |
| Report Date: | October 25, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE-3.6) meeting. The meeting was moderated by Allison Milutinovich and was conducted via videoconference on October 20, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed, and four (4) applications were not discussed
- Panelists: One (1) PDRC Chair/Ad Hoc Reviewer, one (1) PDRC Vice Chair/Ad Hoc Reviewer, three (3) PDRC Members, and one (1) PDRC Member/Ad Hoc 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 was one (1) Conflict 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.

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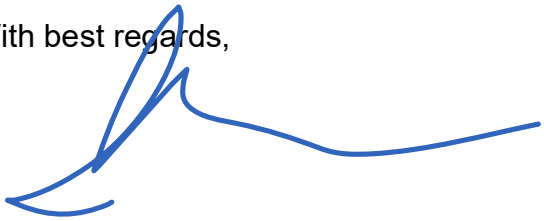

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
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Cameron Eckel, Attorney

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Preliminary Panel-2.8
# (23.1_PDPRE 2.8)
# Observation Report

| | |
|---|---|
| Report No. | 2022-11-01 23.1_PDPRE 2.8 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Preliminary Panel-2.8 (23.1 _PDPRE 2.8) |
| Panel Date: | November 1, 2022 |
| Report Date: | November 4, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Preliminary Panel-2.8 (23.1_PDPRE 2.8) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on November 1, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers/PDRC members
- 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. The COI was excluded from discussions concerning the application for which there was a conflict.

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

## *CONCLUSION*

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

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

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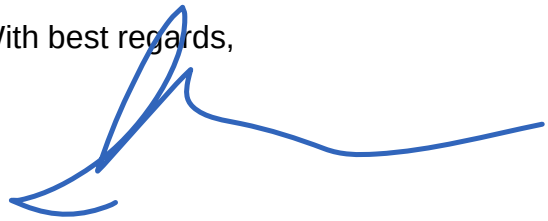
With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
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Cameron Eckel, Attorney

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Preliminary Panel 2.11
# (23.1_PDPRE 2.11)
# Observation Report

| | |
|---|---|
| Report No. | 2022-11-30 23.1_PDPRE 2.11 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Preliminary Panel 2.11 (23.1 _PDPRE 2.11) |
| Panel Date: | November 30, 2022 |
| Report Date: | December 6, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Preliminary Panel 2.11 (23.1_PDPRE 2.11) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on November 30, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair, 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: 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.

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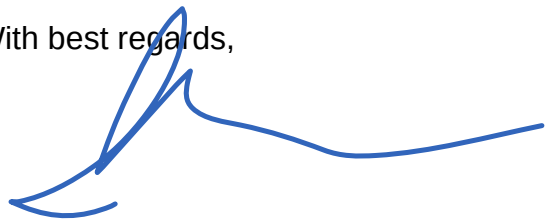
With best regards,



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Cameron Eckel, Attorney

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-1
# (23.1_PDR_PDP1)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-12 23.1_PDR_PDP1 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-1 (23.1 _PDR_PDP1) |
| Panel Date: | December 12, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-1 (23.1_PDR_PDP1) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on December 12, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

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

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

## *CONCLUSION*

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

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

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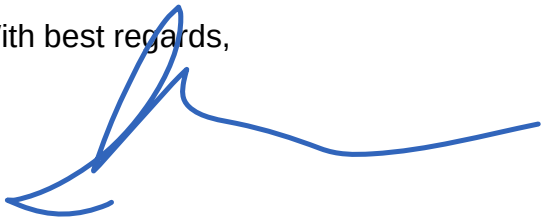
With best regards,



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Cameron Eckel, Attorney

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-2
# (23.1_PDR_PDP2)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-12 23.1_PDR_PDP2 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-2 (23.1 _PDR_PDP2) |
| Panel Date: | December 12, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-2 (23.1_PDR_PDP2) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on December 12, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- 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.

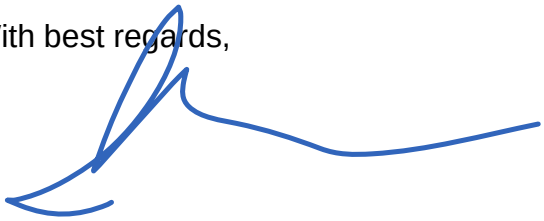
## *CONCLUSION*

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

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

# Re Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-3 (23.1_PDR_PDP3)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-13 23.1_PDR_PDP3 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-3 (23.1 _PDR_PDP3) |
| Panel Date: | December 13, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-3 (23.1_PDR_PDP3) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on December 13, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

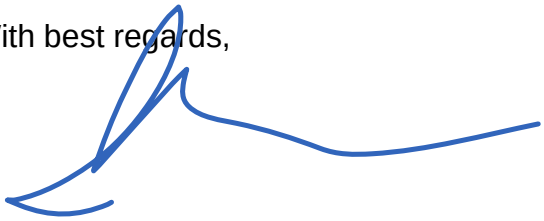
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-4
# (23.1_PDR_PDP4)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-13 23.1_PDR_PDP4 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-4 (23.1 _PDR_PDP4) |
| Panel Date: | December 13, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-4 (23.1_PDR_PDP4) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on December 13, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- 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.

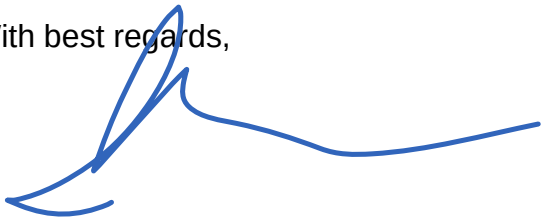
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-5
# (23.1_PDR_PDP5)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-14 23.1_PDR_PDP5 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-5 (23.1 _PDR_PDP5) |
| Panel Date: | December 14, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-5 (23.1_PDR_PDP5) meeting. The meeting was chaired by Bo Saxberg and conducted via videoconference on December 14, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

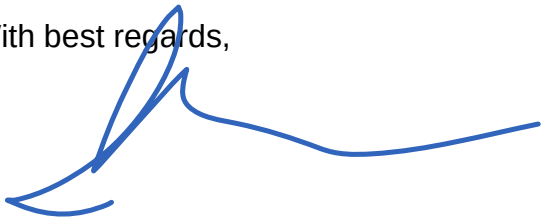
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-6
# (23.1_PDR_PDP6)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-14 23.1_PDR_PDP6 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-6 (23.1 _PDR_PDP6) |
| Panel Date: | December 14, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-6 (23.1_PDR_PDP6) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on December 14, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: 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.

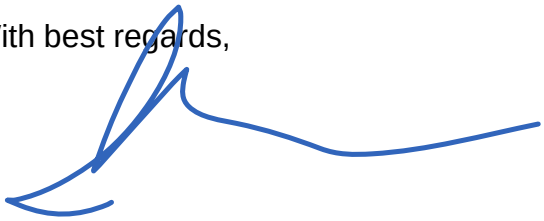
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-7
# (23.1_PDR_PDP7)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-15 23.1_PDR_PDP7 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-7 (23.1 _PDR_PDP7) |
| Panel Date: | December 15, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-7 (23.1_PDR_PDP7) meeting. The meeting was chaired by Alan West and conducted via videoconference on December 15, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) 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: 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 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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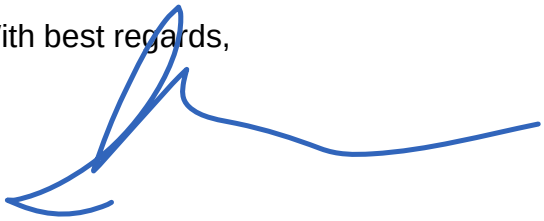
With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-8
# (23.1_PDR_PDP8)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-15 23.1_PDR_PDP8 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-8 (23.1 _PDR_PDP8) |
| Panel Date: | December 15, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-8 (23.1_PDR_PDP8) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on December 15, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

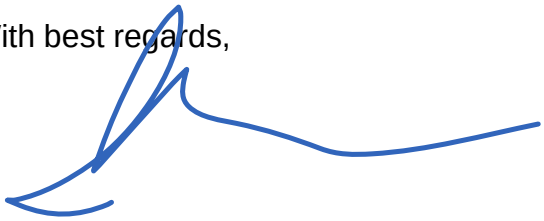
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-9
# (23.1_PDR_PDP9)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-16 23.1_PDR_PDP9 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-9 (23.1 _PDR_PDP9) |
| Panel Date: | December 16, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-9 (23.1_PDR_PDP9) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on December 16, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed
- 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

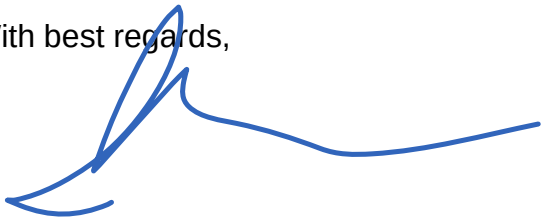
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-10
# (23.1_PDR_PDP10)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-16 23.1_PDR_PDP10 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-10 (23.1 _PDR_PDP10) |
| Panel Date: | December 16, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-10 (23.1_PDR_PDP10) meeting. The meeting was chaired by John McKew and conducted via videoconference on December 16, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

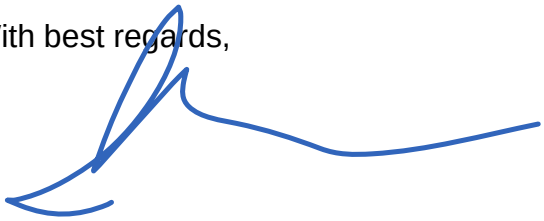
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Prelimenary Panel-1.16
# (23.1_PDPRE 1.16)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-12 23.1_PDPRE 1.16 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Prelimenary Panel-1.16 (23.1 _PDPRE 1.16) |
| Panel Date: | January 12, 2023 |
| Report Date: | January 18, 2023 |

## *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 23.1 Product Development Prelimenary Panel-1.16 (23.1_PDPRE 1.16) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on January 12, 2023.

## *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: Three (3) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel vice chair, 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: 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.

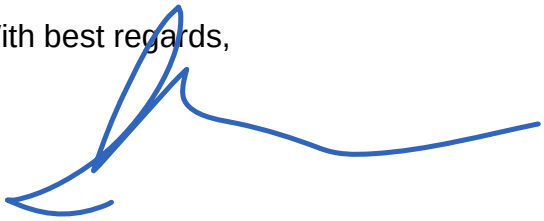
## *CONCLUSION*

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)
# 23.1 Product Development Panel-1 Due Diligence (23.1_PDP-1 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-13 23.1_PDP-1 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-1 Due Diligence (23.1 _PDP-1 DD) |
| Panel Date: | January 13, 2023 |
| Report Date: | January 18, 2023 |

## 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 23.1 Product Development Panel-1 Due Diligence (23.1_PDP-1 DD) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on January 13, 2023.

## 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: 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 (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.

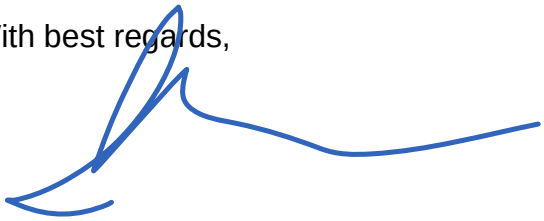
## *CONCLUSION*

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)
# 23.1 Product Development Panel-9 Due Diligence (23.1_PDP-9 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-13 23.1_PDP-9 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-9 Due Diligence (23.1 _PDP-9 DD) |
| Panel Date: | January 13, 2023 |
| Report Date: | January 18, 2023 |

## *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 23.1 Product Development Panel-9 Due Diligence (23.1_PDP-9 DD) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on January 13, 2023.

## *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
- Due Diligence Consultant Evaluators: Two (2)

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.

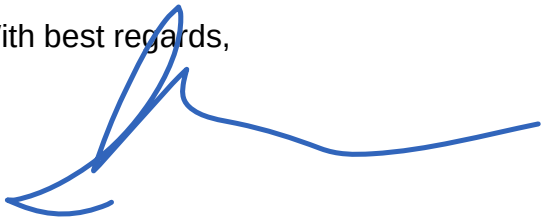
## *CONCLUSION*

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)
# 23.1 Product Development Panel-2 Due Diligence (23.1_PDP-2 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-18 23.1_PDP-2 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-2 Due Diligence (23.1 _PDP-2 DD) |
| Panel Date: | January 18, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-2 Due Diligence (23.1_PDP-2 DD) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on January 18, 2023.

## 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: 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.

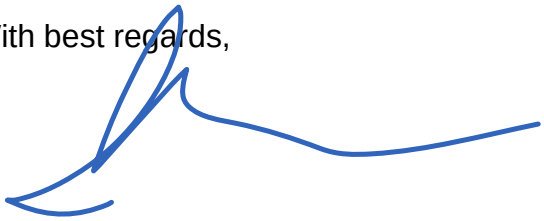
## *CONCLUSION*

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)
# 23.1 Product Development Panel-8 Due Diligence (23.1_PDP-8 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-18 23.1_PDP-8 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-8 Due Diligence (23.1 _PDP-8 DD) |
| Panel Date: | January 18, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-8 Due Diligence (23.1_PDP-8 DD) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on January 18, 2023.

## 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: 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.

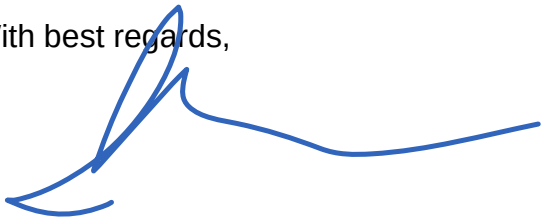
## *CONCLUSION*

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)
# 23.1 Product Development Panel-5 Due Diligence (23.1_PDP-5 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-19 23.1_PDP-5 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-5 Due Diligence (23.1 _PDP-5 DD) |
| Panel Date: | January 19, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-5 Due Diligence (23.1_PDP-5 DD) meeting. The meeting was chaired by Bo Saxberg and conducted via videoconference on January 19, 2023.

## 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, eight (8) 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

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.

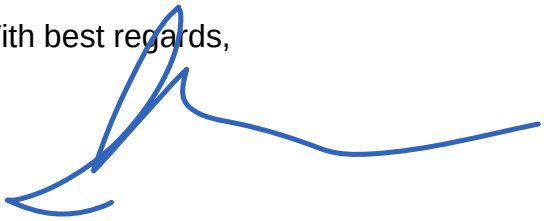
## *CONCLUSION*

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)
# 23.1 Product Development Panel-3 Due Diligence (23.1_PDP-3 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-20 23.1_PDP-3 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-3 Due Diligence (23.1 _PDP-3 DD) |
| Panel Date: | January 20, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-3 Due Diligence (23.1_PDP-3 DD) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on January 20, 2023.

## 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 eight (8) 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.

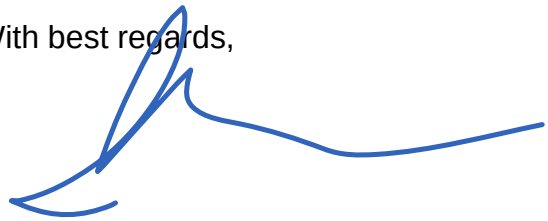
## *CONCLUSION*

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)
# 23.1 Product Development Research - Product Development Review Council Meeting (23.1_PDR-PDRC)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-23 23.1_PDR-PDRC |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research - Product Development Review Council Meeting (23.1 _PDR-PDRC) |
| Panel Date: | January 23, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Research - Product Development Review Council Meeting (23.1_PDR-PDRC) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on January 23, 2023.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, one (1) panel vice-chair and ten (10) 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The COIs did not participate in 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.

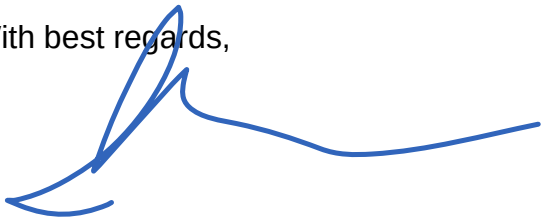
## *CONCLUSION*

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

# Conflicts of Interest Disclosure

## Conflicts of Interest Disclosure

CPRIT Product Development Research Cycle 23.1

Awards Announced at the May 17, 2023, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 23.1 include: *SEED Awards for Product Development Research; Texas New Technologies Company Awards for Product Development Research; Texas Therapeutics Company Awards for Product Development Research* and *Texas Diagnostic and Devices Company Awards for Product Development Research.*

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:** | | | |
| DP230062 | Lewis, Lionel | 7 Hills Pharma LLC | Jones, Elaine |
| DP230066 | Scott, Brenton | Pulmotect, Inc | Geltosky, Jack |
| DP230076 | Stocks, Clifford | OncoResponse | Swiderek, Kristine |
| **Applications not considered by the PIC or Oversight Committee:** | | | |
| DP230031 (preliminary application) | Marija Plodinec | ARTIDIS, Inc | Weinstein, Steve |
| DP230045 (preliminary application) | Carole Spangler Vaughn | Eisana LLC | Swiderek, Kristine |
| DP230015 (preliminary application) | Jason Bock | Resilience Texas LLC dba CTMC | Shoemaker, David |
| DP230093 (preliminary application) | David Arthur | Salarius Pharmaceuticals, Inc. | Jones, Elaine |
| DP230103 | Paola Alvarado | Serene, LLC | Cosan, Roy |

| Application ID | Principal Investigator | Organization | Conflict Noted by Reviewer |
|---|---|---|---|
| (preliminary application) | | | |
| DP230063 (preliminary application) | Mauro Ferrari | BrYet US, Inc. | Canetta, Renzo |

# T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER |
| **SUBJECT:** | T.A.C. § 702.19 WAIVER |
| **DATE:** | FEBRUARY 1, 2023 |

## 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 six companies that the Product Development Review Council (PDRC) has recommended for grant awards. Doing so 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.

The total budget request for the proposed slate of six companies exceeds the remaining funds allocated for FY 2023 product development program awards. Approving this waiver allows Dr. Smith to negotiate proposed budgets and related goals and objectives with the six companies recommended by the PDRC for product development awards prior to final approval by the Oversight Committee. At its February 1 meeting, the Program Integration Committee (PIC) approved deferring final PIC action on the PDRC's recommendations until the May Oversight Committee meeting. The additional time and this waiver serve our goal of reducing the budget requests by an amount such that CPRIT may fund most or all companies recommended by the PDRC. Granting this 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 2023 product development awards.

# High Level Summary of Due Diligence

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- OmniNano Pharmaceuticals LLC for $2,711,437.

The contract contingencies recommended by the PDRC for this award have been satisfied.

OmniNano Pharmaceuticals LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

OmniNano Pharmaceuticals LLC is a Missouri City-based company which is developing a platform using polymeric micellar nanocarrier to codeliver distinctly different drugs to tumors which thereby increases therapeutic concentrations of individual drugs in a simultaneous manner.

Pancreatic ductal adenocarcinoma (PDAC) has a 5-year survival rate of just 11.5% and an overall median survival time of <1 year with the current standard-of-care treatments. This proposal seeks to develop a polymeric micelle-based solution to PDAC based on a micellar co-formulation delivery platform for cyclopamine (CPA), a naturally-occurring compound capable of depleting cancer stem cells, and paclitaxel (PTX), a cytotoxic chemotherapeutic agent that eliminates proliferating cancer cells. In preclinical studies, the polymeric micelles containing both CPA and PTX, named ONP-001, significantly prolonged the median survival of transgenic KPC mice that harbor certain mutations. In a randomized study, ONP-001 increased median survival of mice by 8-fold compared to nab-paclitaxel and by 7-fold compared to gemcitabine. ONP-001 increased the area of benign pancreatic tissue by 270% and substantially reduced poorly differentiated or moderately differentiated tumor cells.2 The strong anti-PDAC efficacy was achieved with a minimal systemic toxicity. ONP-001 overcomes poor drug delivery of therapeutic agents by continuously remodeling tumor stroma to normalize tumor blood vessels and alleviate tumor hypoxia, which leads to increased ONP-001 delivery via a positive reinforcing feedback loop for delivery efficiency. The goals of the proposed project are to manufacture ONP-001 under current Good Manufacture Practice (cGMP) guidance, to conduct GLP-toxicity and toxicokinetic studies (rodents and non-rodents), and to prepare a robust IND (investigational new drug) package to be filed with the FDA.

**Select Reviewer Comments**

*ONP-01 is an innovative product with potential for effective treatment of PDAC.*

*The management team has experience in managing clinical research projects in nanomedicine, as well as on the development of novel drug-delivery systems for selective delivery of diagnostic and therapeutic agents. The team also includes an expert in pharmacokinetics (PK) and pharmacodynamics (PD) of drug formulations.*

*Strong preclinical data that demonstrate feasibility of clinical approach.*

TNTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Resilience Texas LLC dba CTMC for $9,100,000.

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

Resilience Texas LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Cell Therapy Manufacturing Center (CTMC) is a Houston-based joint venture between National Resilience Inc. and MD Anderson Cancer Center (MDACC) to accelerate cell therapy development. There has been a 10-fold increase in cancer cell therapy trials over the last decade. CTMC focuses on three areas to benefit patients and technology by building capacity and differentiated capabilities for retroviral vector (RVV) manufacturing, tumor infiltrating lymphocyte (TIL) platform improvement, and CAR-T process development strategy.

Autologous cell therapies manufacturing process is fraught with bottlenecks that limit treatment access for many patients due to length of time and high production costs. CTMC's current scientific and structural advantages in autologous cell therapy includes a 60,000 SF facility adjacent to MDACC. The project will provide a vertically integrated approach to 1) accelerate novel therapies to the clinic (reduce time from research to clinical proof of concept) 2) provide a robust strategy to move products from clinical proof of concept to commercialization, and 3) drive down the long-term commercial cost of cellular therapy products.

There are few manufacturing centers that focus on retroviral vectors, and little to no development of downstream process development of the RVV. CTMC will utilize a two-pronged approach: optimized transient transfection to make RVV for a fast-to-clinic strategy as well as development of a robust clonal pools, selected clones, and downstream purification RVV process to support a

streamlined approach for later stage therapies which will provide a reduced overall development timeline.

TIL therapy is a proven and effective option in melanoma, and much of the development of successful manufacturing processes done by the scientific staff that moved from MDACC to CTMC. The project will utilize CTMC's prior expertise in TIL optimization to improve the second phase of the process through final formulation. These improvements will develop a robust and broadly applicable potency assay that is currently lacking in the field, which will open doors for exploration of novel engineering in the TIL field, expansion to additional cancer indications.

Autologous cellular therapies require dedicated equipment, highly trained operators, and individual manufacturing for each patient. CAR-T processes are typically developed solely with healthy donor blood products and standard/unoptimized cryopreservation methods. CTMC proposes to develop scale-down models, accessing and incorporating patient samples during development with quicker and less costly evaluation of automated steps, and by developing data-driven methods for freezing products based on cryopreservation strategies.

The proposal provides that CTMC establish a robust and flexible center for retroviral vector (RVV) manufacturing in Texas; Expand platform expertise by optimizing tumor infiltrating lymphocyte (TIL) manufacturing and provide a differentiated process development approach for CAR-T manufacturing.

**Select Reviewer Comments**

**"***Major strengths of the application include the objectives, which have identified bottle necks in RRV, CAR-T, and TIL manufacturing and propose innovative strategies to overcome them. The close partnership with MD Anderson and a regulatory staff, which allows for essentially 1-stop preclinical to clinical development of cell-based therapeutics, is highly innovative."*

**"***This is a very innovative concept and structure potentially addressing some of the challenges in the cell and gene therapy space … builds permanent jobs in Texas and adds to the needed biotech infrastructure to create a true biotech/oncology ecosystem."*

*"The development plan indicates an opportunity to further research and develop a technology that will save time to get treatment to patients."*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Alterum Therapeutics LLC for $11,721,150.

The contract contingencies recommended by the PDRC for this award have been satisfied.

Allterum Therapeutics LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Allterum Therapeutics LLC is a Houston-based preclinical company formed around research conducted at National Cancer Institute of a monoclonal antibody, 4A10, against CD127 as a treatment for acute lymphoblastic leukemia (ALL). CD127 is a subunit for both the interleukin-7 receptor (IL-7R) and the TSLP receptor, which are expressed on T-Cell ALL and pre-B Cell ALL, respectively. 4A10 binds CD127 and exerts its anticancer activity by a dual mechanism: inhibition of IL-7 signaling and cytotoxicity via ADCC mediated by its IgG1 Fc region. 4A10's anti-cancer activity in ALL has been demonstrated both in vitro and in vivo in multiple labs, including patient-derived xenograft (PDX) models.

There are about 7,000 cases of ALL in the U.S. each year with ~1,600 deaths. ~80% of ALL patients are children, making it the most common childhood cancer in the U.S. ~80% of ALL patients have pre-B cell ALL (B-ALL) and ~20% have T-cell ALL (T-ALL). ALL treatment is a relative success story in cancer. Both B-ALL and T-ALL patients receive a similar first-line regimen, to which ~85% respond. Several options exist for patients with B-ALL who progress after first-line therapy, but a third will still progress or be unable to tolerate available treatments. Patients with T-ALL who progress have an even poorer prognosis, with no approved targeted second-line options. Patients with relapsed or refractory (r/r) ALL have poor outcomes with a 15-35% five-year survival, and are the initial focus of our development.

4A10 is expected to be well tolerated and active even in relapsed disease, it would be attractive to patients who have failed or cannot tolerate other available therapies. The clinical goal of the project is to get a complete response without minimal residue disease making the patient eligible for a potentially curative stem cell transplant. The long-term goal is to expand the label to add 4A10 to standard first-line therapy to increase effectiveness and/or decrease toxicity.

A prior CPRIT Seed award supported scale up 4A10 manufacturing, conduct early toxicological studies, develop clinical protocol, and obtain pre-IND guidance from FDA. 4A10 has received orphan drug and pediatric rare disease designation in ALL. The proposal provides that Allterum will Manufacture of Drug Substance (DS) and Drug Product (DP) under GMP; Perform Pivotal GLP Toxicology Studies to support IND filing; Submit IND and IRB filings and initiate clinical trial site(s) for the Phase I/IIA Clinical Trial of 4A10 in Patients with relapsed/refractory Acute Lymphoblastic Leukemia (r/r ALL); and Conduct First-in-Human Phase I/IIA Clinical Trial for 4A10 in r/r ALL patients.

**Select Reviewer Comments**

*"There is an unmet need for treating recurring or resistant forms of ALL. This applicant is proposing the development of a product to provide benefit to these patients with a low-toxicity product … The applicant has had a pre-IND meeting with the FDA and has incorporated the FDA recommendations into their study design, ie, monotherapy for 28 days. Additionally, the applicant indicates that they have already received orphan drug and pediatric rare disease designation for 4A10 in ALL."*

*"This proposal is very Texas-centric, and the conduct of this work will further both CPRIT's goals and successes."*

*"Novel effective treatment options for relapsed/refractory ALL are needed, and the intended product that targets CD127 could satisfy an unmet need for treatment."*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- 7 Hills Pharma LLC for $13,439,001.

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

7 Hills Pharma LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

7 Hills Pharma LLC is a Houston-based company which is developing 7HP349 which is a first-in-class, oral, small molecule, positive allosteric modulator of integrins critical for immune surveillance (immune cell priming, trafficking and effector functions) that may increase the effectiveness of CPI, with a low risk of elevated immunotoxicities, in PD-1 resistant cancers.

7HP349 as systemic drug has been shown to have single-agent antitumor activity, is synergistic with PD-(L)1, aCTLA-4, and immunogenic doses of radiation with tumor-selective homing of antigen-specific T cells. The priming dose, schedule, and plasma exposures have been defined in multiple mouse tumor and infectious disease models. 7HP349 has been shown not to increase immunotoxicies.

In a Phase I healthy volunteer study, 7HP349 was orally bioavailable with a safety margin of >10x based on the optimal pharmacokinetic (PK) exposures with a minor positive food effect. The single dose and repeat dose PK were non-linear, and the T ½ of ~20h supported once-daily

dosing. 7HP349 doses of 100-300 mg will be dose escalated in combination with ipilimumab and nivolumab.

7 Hills has developed scalable, low-cost manufacturing processes and estimate ambient stability of 5 and 3 years for the 7HP349 Drug Substance (DS) and Product (DP). 16 kg of cGMP DS and 30,000 capsules of DP have been produced and will be ready for clinical use in 2Q2023.

US FDA has granted 7HP349 Orphan Drug designation for treatment of malignant melanoma stages IIB to IV and Fast Track designation for 7HP349 in combination with a CTLA-4 inhibitor for the treatment of patients with unresectable or metastatic *MM* following prior PD-1 inhibitor treatment.

The proposed project aims to establish target-centric patient selection biomarker; manufacture and release of cGMP 7HP349 Drug Product(s) (DP), and complete registrational ICH stability programs; complete the 7HP111, Phase Ib/IIa clinical trial to determine the safety and efficacy of oral 7HP349 in combination with ipilimumab followed by nivolumab in patients with locally advanced or metastatic malignancies (melanoma, HNSCC, NSCLC) resistant to or relapsing after PD-1 inhibitor therapy.

**Select Reviewer Comments**

*"The application states that over 40% of patients with metastatic melanoma are resistant to checkpoint inhibitor therapies. An oral medication that can increase the effectiveness of current immunotherapies without an increase in toxicities would be of benefit to such patients."*

*"7 Hills Pharma is pursuing an unmet medical need with a novel mechanism targeting resistant metastatic melanoma patients with aPD-1 resistance by enhancing ICI effectiveness with 7HP349, a first-in-class, oral, small-molecule, positive allosteric modulator of integrins critical for immune cell priming, T cell trafficking and effector functions."*

*"7 Hills Pharma has presented impressive in vivo pharmacodynamic effects with 7HP349 including significant inhibition of tumor growth and increased response rate in combination with aPD-1 and aCTLA-4 immune checkpoint inhibitors and effected an increase in the recruitment of CD4 and CD8 T cells into the tumor. "*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Pulmotect Inc. for $8,851,165.

The contract contingencies recommended by the PDRC for this award have been satisfied.

Pulmotect Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Pulmotect, Inc. is a Houston-based company which is developing an immunomodulatory technology to treat and prevent respiratory infections in immunocompromised cancer patients to improve cancer patient outcomes. PUL-042 inhalation solution contains two active ingredients, which act synergistically on Toll-like receptors to stimulate pulmonary epithelial innate immunity and protect against a wide range of pathogens.

Respiratory infections are caused by a variety of pathogenic organisms including viruses, bacteria, and fungi. Cancer patients are highly susceptible to respiratory infection and potentially lethal pneumonia due to suppressed *adaptive* immunity. Pneumonia is second only to the underlying cancer in causing death in cancer patients.

Cancer patients still have intact respiratory epithelium that can respond to stimuli. By stimulating these *innate epithelial immune responses* in the lung and enhancing the ability to fight off invading pathogens, patients can be protected from pulmonary infections, thereby reducing morbidity and mortality. PUL-042, is administered by inhalation and activates the lung epithelial innate defense mechanisms through stimulation of specific lung epithelial Toll-like receptors providing broad protection against invading pathogens. Extensive *in vitro* and *in vivo* preclinical experiments and toxicology studies have demonstrated safety and broad protection against pathogens. PUL-042 has clinical evidence of anti-viral activity against the SARS-CoV-2 virus in a Phase 2 clinical trial. Data in more than 200 PUL-042 treated subjects demonstrate safety and clinical proof of concept thereby increasing the probability of successful development.

Pulmotect proposes to Initiate a Phase 2 Clinical Trial; Complete Patient Enrollment and Complete Final Study Report:

**Select Reviewer Comments**

*Pulmonary infection (pneumonia) among immunocompromised patients is a well established area of unmet clinical need, accounting for the proximate cause of mortality among many hospitalized patients. A "pathogen" agnostic therapeutic modality would have widespread applications.*

*Given the high mortality from pneumonia in immunocompromised cancer patients, the challenges of rapid diagnosis and treatment of one or multiple lung infections and the promise of prophylaxis and/or treatment of viral, bacterial or fungal infections by stimulation of innate immunity in the lung, there is tremendous unmet need and potential for PUL-042.*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- OncoResponse for $13,259,174.

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

OncoResponse Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

OncoResponse is a Seattle-based company which is developing OR502 which is a humanized monoclonal antibody for treatment of advanced human malignancies. The target of OR502 is the leukocyte immunoglobulin-like receptor-2/immunoglobulinlike transcript-4 (LILRB2/ILT4) protein which is expressed on the surface of certain immune cells known to play a role in immune response to cancer. OR502 disrupts immuoinhibitory actions of LILRB2, leading to immune stimulation and potentiation of anti-cancer responses.

OR502 is a humanized monoclonal antibody that binds with high affinity and specificity to an epitope on LILRB2 distinct from all other clinical candidates, including MK-4830. OR502 demonstrates specific binding to myeloid cells, no binding to a panel of other immune cells, and potently blocks the interaction of LILRB2 with HLA-G and other HLA-class I molecules. In pre-clinical studies, OR502 demonstrates superior characteristics versus competitors. OR502 outperforms MK-4830 in restoring CD8+ T-cell proliferation, interferon gamma and perforin secretion in M2c/CD8+ T cell coculture assay and rescues interferon gamma production in M2c/Exhausted CD8+ T cell coculture assays. OR502 has 2-pronged functionality, as it reduces the immunosuppressive phenotype of existing tumor associate macrophages (TAMs) and prevents development of new immunosuppressive TAMs.

OncoResponse is developing an OR502-expressing cell line, cell culture process, purification process, analytical methods, and formulation and completed a manufacturability assessment which showing excellent characteristics.

OR502 will be developed for the treatment of solid tumors. The development plan will first determine the safe dose of OR502 in subjects with advanced solid malignancies for which no standard therapies exist, and then evaluate additional safety and potential activity in tumor-specific expansion cohorts. The Phase 1 study will use an efficient dose-escalation design to rapidly determine a safe and potentially efficacious dose and schedule. Concurrent with

monotherapy dose escalation, combination cohorts with an anti-PD-(L)1 will be enrolled to evaluate safety of OR502 in combination.

OncoResponse's proposal provides for completing all IND-enabling studies for OR502 and file NDA with FDA; initiating Phase 1A clinical trials to assess safety and dose level; completing Phase 1A trials and establish RP2D (monotherapy and in combination with anti-PD-1; initiating dose-expansion for 2 indications (monotherapy and in combination); initiating monotherapy biology cohort and conduct additional biomarker analysis and assessing initial ORR for initial patients in expansion and biology cohorts

**Select Reviewer Comments**

*The management team is very strong and experienced, including the CEO who has many years of experience in raising venture capital and mergers and acquisitions. The CMO is a medical oncologist who trained at NIH and has many years of experience in the pharmaceutical industry. The CSO is experienced in biomarker development and generating preclinical data.*

*This is a validated target with potential for addressing important unmet/emerging needs in a variety of cancers.*

*This is a very strong resubmission of an application focused on addressing the unmet need in ICI response.*

# De-Identified Overall Evaluation Scores

# Texas New Technologies Company Awards for Product Development Research

Product Development Research Cycle 23.1

*Full Application Review*

| Application ID | Final Overall Score |
|---|---|
| DP230079* | 2.3 |
| aaa | 5.1 |

* Recommended for award.

# Texas New Technologies Company Awards for Product Development Research

Product Development Research Cycle 23.1

*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 |
|---|---|
| Ba | 3.8 |
| Bb | 4.5 |
| Bc | 4.8 |
| Bd | 5.3 |
| Be | 7.0 |

* Recommended for full application review.

# Final Overall Evaluation Scores and Rank Order Scores

January 30, 2023

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

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

Dr. Patel and Mr. Roberts,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 23.1 grant award cycle. The PDRC convened on January 23, 2023 and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Resilience Texas LLC dba CTMC, Allterum Therapeutics, LLC, 7 Hills Pharma, LLC, Pulmotect, Inc., OmniNano Pharmaceuticals LLC, OncoResponse. The attached table reflects the ranked award recommendation for the six (6) grant applications that CPRIT would like deferred to the May 2023 Oversight Committee meeting.

The PDRC did not make any changes to timelines or budgets for the six (6) projects recommended for funding. However, four (4) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP230071, DP230076, and DP230079 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP230066 related to clinical data and statistical analysis. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

# FY23.1 Product Development Review Council Recommendations

| Ranking | ID | Mechanism | Type | PI Last Name | Application Title | Organization | Score from Due Diligence | Budget |
|---|---|---|---|---|---|---|---|---|
| 1 | DP230079 | TNTC | New | Bock, J | Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value-Added Biotech Partnerships | Resilience Texas LLC dba CTMC | 2.3 | $12,000,000 |
| 2 | DP230062 | TTC | New | Lewis, L | 7HP349, a Small Molecule, Oral Integrin Activator to Treat Patients With anti-PD-1 Resistant Melanoma | 7 Hills Pharma LLC | 2.6 | $18,679,381 |
| 3 | DP230064 | SEED Therapeutics | New | Ma, G | IND-Enabling Studies of ONP-001: A Nano-Codelivery Formulation with Two Drugs of Distinct Mechanisms of Action for Treating Pancreatic Ductal Adenocarcinoma | OmniNano Pharmaceuticals LLC | 3.3 | $2,999,858 |
| 4 | DP230076 | TTC | New | Stocks, C | OncoResponse OR502 anti-LILRB2 monoclonal antibody Phase 1-2 clinical study | OncoResponse | 3.6 | $19,326,953 |
| 5 | DP230066 | TTC | Resubmission | Scott, B | Improving Cancer Patient Outcomes by Activating Lung Innate Immunity | Pulmotect, Inc. | 3.3 | $12,445,092 |
| 6 | DP230071 | TTC | Resubmission | Varadhachary, A | Clinical development of a novel CD127 antibody for treating patients with relapsed/refractory Acute Lymphoblastic Leukemia (ALL) | Allterum Therapeutics, LLC | 2.6 | $17,005,376 |

Cancer Prevention & Research
Institute of Texas

# CEO Affidavit
# Supporting Information

**Product Development Research**
**FY 2023—Cycle 1**
***Texas Therapeutics Company Awards for Product Development Research***

# Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS
# RFA 23.1-TTC

## Texas Therapeutics Company Awards for Product Development Research

**Please also refer to the Instructions for Applicants document, which CPRIT will post August 24, 2022**

**Preliminary Application Receipt Opening Date:** August 24, 2022

**Full Application Receipt Closing Date:** May 1, 2023

**FY 2023**

Fiscal Year Award Period

September 1, 2022-August 31, 2023

## TABLE OF CONTENTS

# RFA VERSION HISTORY

Rev 8/24/2022 RFA release

Rev 10/11/2022 Section 6.4 – Preliminary and Full Application Submission Deadlines

- Edited to clarify how many full applications will be reviewed in the first full application review cycle

Section 8.3 – Goals and Objectives (G&Os)

- Edited to clarify that G&Os in the full application should not vary significantly from the aims presented in the preliminary application

Section 8.12 – Budget

- Edited to clarify that the total budget included in the full application must not vary significantly from the anticipated budget request included in the applicant's preliminary application

# 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 at any time, which a panel of experts will review within 3 to 5 weeks of receiving the submission. If the preliminary application demonstrates sufficient scientific merit and appears to be an appropriate fit for CPRIT's portfolio, CPRIT will invite the company 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. For planning purposes, CPRIT's review schedule links panel presentation dates and final award decisions to the 3 application submission deadlines offered per CPRIT's fiscal year (September 1-August 31).

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.

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 contemporaneous 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." 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 FY 2023 are as follows:

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

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/IDE 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 concept (safety and efficacy)
- Chemistry, manufacturing, and controls (CMC)/manufacturing development
- GLP safety studies to support INDs
- Phase 1 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

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

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

If appropriate, the applicant may propose one 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. Resubmission Policy

For the FY 2023 review cycle, CPRIT will consider the company's first preliminary application, and subsequent full application if CPRIT invites the company to submit a full application, as a new application, even if the company previously applied prior to August 24, 2022.

A company may resubmit a preliminary application 1 time (for a total of 2 submissions) during the FY 2023 review cycle. 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. 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 2-step process to review company projects proposed for funding. An integrated panel of individuals with expertise in biotechnology and basic/translational/clinical cancer research as well as regulatory approval processes will review all applications. Cancer patient advocates also participate in the review of full applications.

All 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. 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.

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.

The company may submit a preliminary application at any 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. The review process ends after preliminary review for those applicants not invited to submit a full application.

Absent unusual circumstances, CPRIT will notify the applicant of the outcome of the preliminary review within 3 to 5 weeks.

## 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 also convenes virtually for the applicant to present the application in-person and respond to reviewers' questions.

### 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 aspects, manufacturability, and market assessments. The applicant should be prepared to provide CPRIT with any correspondence that the company has conducted with regulatory agencies (eg, the FDA).

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 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 support expectations of clinical impact
- Proposed Integrated Product Development Plan (IPDP)
- 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 one 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.** Applicants must create a CARS user account to generate and submit the application. The *Instructions for Applicants* associated with this RFA provides information about establishing a user account.

## 6.2. Invitations to Submit Full Applications Valid Only for the FY 2023 Review Process

The invitation to submit a full application is valid only for the FY 2023 review cycle. This means that a company must submit its full application no later than May 1, 2023, for CPRIT to consider the project for FY 2023 award funding. An applicant invited to submit a full application in FY 2023 but does not do so must restart the review process in a future cycle by resubmitting the preliminary application. However, the resubmission will not count against the limit in CPRIT's resubmission policy.

## 6.3. CPRIT May Elect to Close the FY 2023 Review Cycle Early If Funds Are Unavailable

Applicants should be cognizant that CPRIT has limited funds available to fund Product Development Awards (approximately $70 million for the FY 2023 review cycle). CPRIT may cease accepting applications for the FY 2023 review cycle and/or defer applications to the FY 2024 review cycle if the amount approved for FY 2023 Product Development Awards exceeds $70 million prior to the close of the FY 2023 review cycle.

## 6.4. Preliminary and Full Application Submission Deadlines; Other Key Dates

Preliminary Applications: An applicant may submit a preliminary application via CARS at any time on or after August 24, 2022.

Full Applications: CPRIT will convene review panels up to 3 times during the FY 2023 review process for in-person presentations of full applications. Invited applicants may elect to submit the full application by one of the deadlines listed below, and the next available review panel will consider the application. Key dates for the FY 2023 review cycles are as follows:

| **FY 2023 Review Cycle 1** | |
|---|---|
| Full Application Deadline | November 1, 2022; 4:00 PM central time |
| In-Person Presentation | Week of December 12, 2022 |
| Due Diligence | December 2022-January 2023 |
| Oversight Committee Meeting | February 15, 2023 |

| **FY 2023 Review Cycle 2** | |
|---|---|
| Full Application Deadline | February 1, 2023; 4:00 PM central time |
| In-Person Presentation | Week of March 13, 2023 |
| Due Diligence | March-April 2023 |
| Oversight Committee Meeting | May 17, 2023 |

| **FY 2023 Review Cycle 3** | |
|---|---|
| Full Application Deadline | May 1, 2023; 4:00 PM central time |
| In-Person Presentation | Week of June 12, 2023 |
| Due Diligence | June-July 2023 |
| Oversight Committee Meeting | August 16, 2023 |

CPRIT will endeavor to assign all applications received by the review cycle deadline to the next available in-person presentation panel. However, if the number of applications received by the deadline exceeds the review panel's ability to provide a thorough, fair review, CPRIT will use its discretion to assign the application to a future review panel. Due to schedule constraints, CPRIT has the capacity to review no more than 10 full applications in the first review cycle (full application deadline November 1, 2022). If the number of full applications submitted by the November 1 deadline exceeds 10, then CPRIT will review the first 10 full applications submitted in CARS as reflected by the date/time of the submission. For those full applications submitted in the first review cycle but not reviewed, CPRIT will defer the review to the second review cycle (full application deadline February 1, 2023).

## 6.5. Submission Deadline Extensions

In-person panel presentation schedules are set in advance and do not accommodate receipt of a 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 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 a minimum of 5 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.

## 6.6. 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 make the payment by check or money order payable to "Cancer Prevention and Research Institute of Texas." Indicate the application ID and the name of the submitter on the check. CPRIT will not accept electronic and 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. 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. Brief description of asset/technology
b. Target/mechanism of action
c. Initial target indication(s)/patient populations: tumor type(s), stage, extent of prior standard of care (SOC) therapy
d. Unmet medical need of initial target indications
e. 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
f. Characteristics of agent/target interaction: potency, reversibility, selectivity, pharmacodynamic (PD) effects
g. In vitro preclinical efficacy characterization (eg, cell lines tested with corresponding EC50s selectivity vs normal cells; potency vs competitive agents)
h. In vivo preclinical efficacy characterization (list animal models tested; potency vs SOC; tumor growth inhibition vs tumor regression; effects on survival; combination studies)
i. In vivo tumor data supporting in vivo proof of concept
j. ADME, pharmacokinetics (PK), TK (brief statement addressing status of key studies and results if available)
k. Safety characterization to date
l. Biomarker candidates, if any, for companion diagnostic test development
m. Manufacturing/CMC development status
n. Clinical trial status and plans forward to be covered by the grant

o. Regulatory status and plan (eg, agency interactions to date and planned, likely regulatory paths)
p. 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
q. Potential competitive advantages together with supporting rationale
r. Senior management team accomplishments in cancer drug development
s. Company financial status/fundraising plans

### 7.2. 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.

### 7.3. 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.

## 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.

### 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 one 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. Brief description of asset/technology
b. Target/mechanism of action
c. Initial target indication(s)/patient populations: tumor type(s), stage, extent of prior SOC therapy
d. Unmet medical need of initial target indications

e. 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
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 vs normal cells; potency vs competitive agents)
h. In vivo preclinical efficacy characterization (list animal models tested; potency vs SOC; tumor growth inhibition vs tumor regression; effects on survival; combination studies)
i. In vivo tumor data supporting in vivo proof of concept
j. ADME, PK, TK (brief statement addressing status of key studies and results if available)
k. Safety characterization to date
l. Biomarker candidates, if any, for companion diagnostic test development
m. Manufacturing/CMC development status
n. Clinical trial status and plans forward to be covered by the grant
o. Regulatory status and plan (eg, agency interactions to date and planned, likely regulatory paths)
p. 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
q. Potential competitive advantages together with supporting rationale
r. Senior management team accomplishments in cancer drug development
s. Company financial status/fundraising plans

## 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 1 page)

If the applicant submitted a preliminary or full application to CPRIT prior to August 2022 or if the applicant is resubmitting a preliminary or full application already submitted in the FY 2023 review cycle, upload a summary of the 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 application 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

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 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, 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 (Y/N)
    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 meds
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, eg, CRs. In the case of OS/PFS 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 FDA guidelines 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 8.8.9, the applicant must provide any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as FDA, EMEA, 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.
     - Clastogenecity: 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 NHP
   - 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 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 (TGI) 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 8.8.9, the applicant must provide any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as FDA, EMEA, 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 CRO input into budget preparation.

### 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 8.8.9, the applicant must provide any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as FDA, EMEA, 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. NOTE: Applicants must separately upload into CARS as a standalone document any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as FDA, EMEA, 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 application review process.** If the applicant receives meeting minutes after submitting the application but before CPRIT has made a final decision on the application, the application should contact the CPRIT Helpdesk (see section 10.1) for assistance on filing the additional information.

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 mostly 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 (iPSP) 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.

## 8.9. Business Plan (maximum 11 pages)

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. 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.

### 8.9.10. 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. 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" 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 FY 2023 annual salary is $200,000. An individual may request salary proportional to the percent effort up to a maximum of $200,000. 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 $200,000. CPRIT may revise the FY 2023 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 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 $1 of funds under the company's control for every $2 of CPRIT grant award funds.
- A company approved for one or more CPRIT product development grants that together total a commitment of more than $20 million must increase their matching fund obligation to $1 for every $1 contributed by CPRIT.
  The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under CPRIT's matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.
- A company approved for one or more CPRIT product development grants that together total a commitment of more than $30 million must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

# 10. CONTACT INFORMATION

## 10.1. Helpdesk

The Helpdesk will answer queries submitted via email within one 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.

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| 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: | Help@CPRITGrants.org |
| Website: | www.cprit.texas.gov |

# 11. APPENDIX - REVIEWER EVALUATION GUIDELINES

## 11.1. Primary Review Criteria (Scored)

### 11.1.1. Unmet Medical Need: Target Product Profile (TPP)

a. Assuming successful accomplishment of development objectives, as reflected in the target product profile, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
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-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 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 (United States/European Union)? Do development proposals reflect specific regulatory authority input; eg, from pre-IND interactions? Alternatively, has regulatory authority interaction been insufficient so far?
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)
# 23.1 Product Development Research Preliminary Application Review 1.1 (23.1 _PDPRE 23.1 - 1.1)
# Observation Report

| | |
|---|---|
| Report No. | 2022-09-22 23.1_PDPRE 23.1 - 1.1 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review 1.1 (23.1 _PDPRE 23.1 - 1.1) |
| Panel Date: | September 22, 2022 |
| Report Date: | September 28, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Preliminary Application Review 1.1 (23.1_PDPRE 23.1 - 1.1) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on September 22, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair and three (3) PDRC members
- 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.

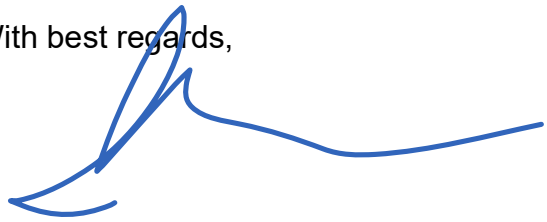
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.2)
# Observation Report

| | |
|---|---|
| Report No. | 2022-09-26 23.1_PDPRE 2.2 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 2.2) |
| Panel Date: | September 26, 2022 |
| Report Date: | September 28, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.2) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on September 26, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and one (1) application was not discussed
- Panelists: One (1) panel chair, three (3) PDRC members
- 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 (COIs) identified prior to and/or during the meeting.

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

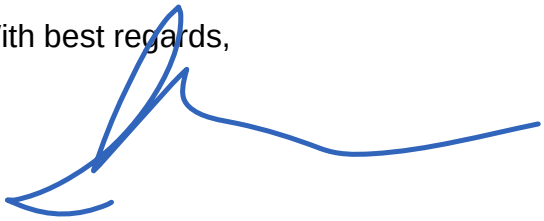
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 1.4)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-06 23.1_PDPRE 1.4 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 1.4) |
| Panel Date: | October 6, 2022 |
| Report Date: | October 11, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 1.4) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on October 6, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed
- Panelists: One (1) panel chair, and three (3) PDRC members
- 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.

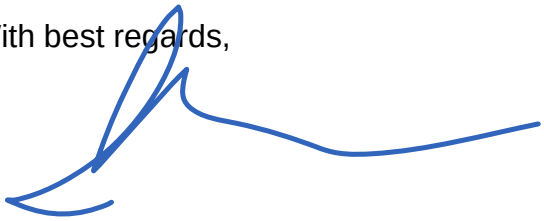
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 3.3)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-06 23.1_PDPRE 3.3 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 3.3) |
| Panel Date: | October 6, 2022 |
| Report Date: | October 11, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 3.3) meeting. The meeting did not have chair and was conducted via videoconference on October 6, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Three (3) applications were discussed and two (2) applications were not discussed
- Panelists: No (0) panel chair, and four (4) PDRC members
- 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.

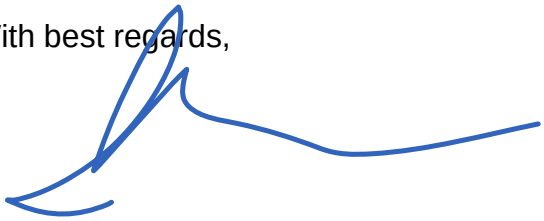
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.5)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-13 23.1_PDPRE 2.5 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE 2.5) |
| Panel Date: | October 13, 2022 |
| Report Date: | October 19, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE 2.5) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on October 13, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and four (4) applications were not discussed
- Panelists: One (1) panel chair, and three (3) PDRC members
- 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 two (2) Conflicts of Interest (COIs) identified prior to the meeting, and one potential COI identified during the meeting. COIs were excluded from discussions concerning applications for which there was a conflict.

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

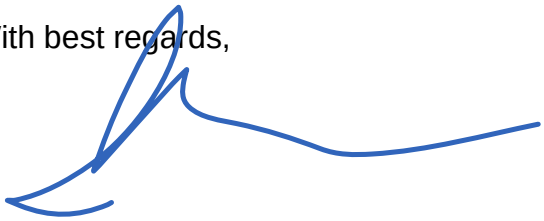
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE-3.6)
# Observation Report

| | |
|---|---|
| Report No. | 2022-10-20 23.1_PDPRE-3.6 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Preliminary Application Review (23.1 _PDPRE-3.6) |
| Panel Date: | October 20, 2022 |
| Report Date: | October 25, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Preliminary Application Review (23.1_PDPRE-3.6) meeting. The meeting was moderated by Allison Milutinovich and was conducted via videoconference on October 20, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## SUMMARY OF OBSERVATION RESULTS

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Four (4) applications were discussed, and four (4) applications were not discussed
- Panelists: One (1) PDRC Chair/Ad Hoc Reviewer, one (1) PDRC Vice Chair/Ad Hoc Reviewer, three (3) PDRC Members, and one (1) PDRC Member/Ad Hoc 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 was one (1) Conflict 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

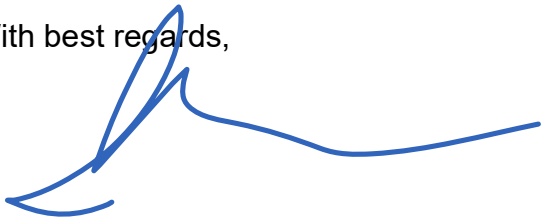
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Preliminary Panel-2.8
# (23.1_PDPRE 2.8)
# Observation Report

| | |
|---|---|
| Report No. | 2022-11-01 23.1_PDPRE 2.8 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Preliminary Panel-2.8 (23.1 _PDPRE 2.8) |
| Panel Date: | November 1, 2022 |
| Report Date: | November 4, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Preliminary Panel-2.8 (23.1_PDPRE 2.8) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on November 1, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers/PDRC members
- 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. The COI was excluded from discussions concerning the application for which there was a conflict.

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

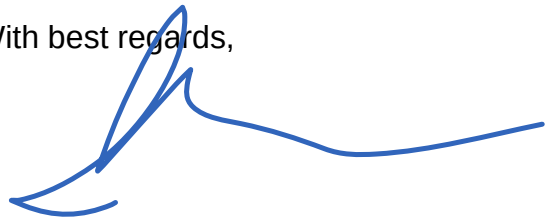
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Preliminary Panel 2.11
# (23.1_PDPRE 2.11)
# Observation Report

| | |
|---|---|
| Report No. | 2022-11-30 23.1_PDPRE 2.11 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Preliminary Panel 2.11 (23.1 _PDPRE 2.11) |
| Panel Date: | November 30, 2022 |
| Report Date: | December 6, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Preliminary Panel 2.11 (23.1_PDPRE 2.11) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on November 30, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Two (2) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel chair, 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: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

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

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

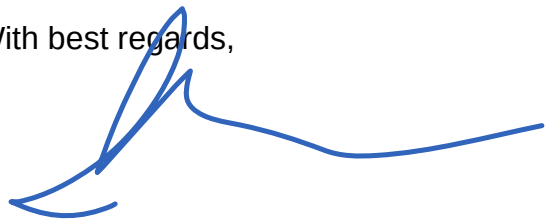
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-1
# (23.1_PDR_PDP1)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-12 23.1_PDR_PDP1 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-1 (23.1 _PDR_PDP1) |
| Panel Date: | December 12, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-1 (23.1_PDR_PDP1) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on December 12, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

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

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

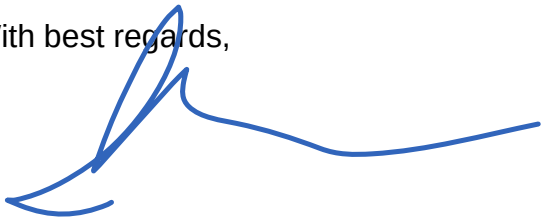
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-2
# (23.1_PDR_PDP2)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-12 23.1_PDR_PDP2 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-2 (23.1 _PDR_PDP2) |
| Panel Date: | December 12, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-2 (23.1_PDR_PDP2) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on December 12, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- 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.

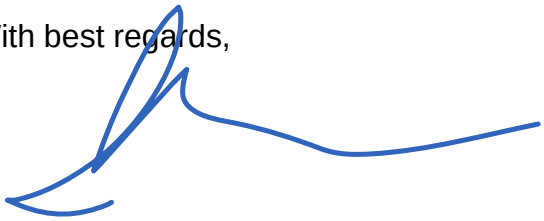
## *CONCLUSION*

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

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

# Re Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-3 (23.1_PDR_PDP3)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-13 23.1_PDR_PDP3 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-3 (23.1 _PDR_PDP3) |
| Panel Date: | December 13, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-3 (23.1_PDR_PDP3) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on December 13, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

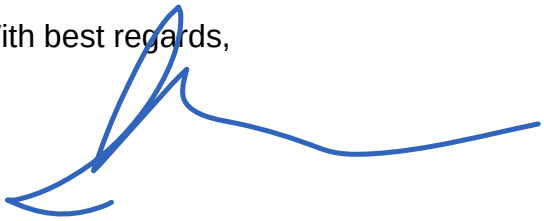
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-4
# (23.1_PDR_PDP4)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-13 23.1_PDR_PDP4 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-4 (23.1 _PDR_PDP4) |
| Panel Date: | December 13, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-4 (23.1_PDR_PDP4) meeting. The meeting was chaired by Kelly Bolton and conducted via videoconference on December 13, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: 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: Five (5)
- 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.

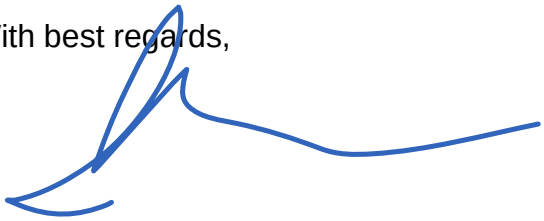
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-5
# (23.1_PDR_PDP5)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-14 23.1_PDR_PDP5 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-5 (23.1 _PDR_PDP5) |
| Panel Date: | December 14, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-5 (23.1_PDR_PDP5) meeting. The meeting was chaired by Bo Saxberg and conducted via videoconference on December 14, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

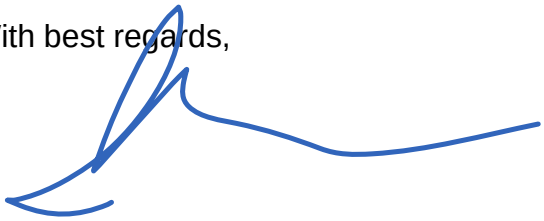
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-6
# (23.1_PDR_PDP6)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-14 23.1_PDR_PDP6 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-6 (23.1 _PDR_PDP6) |
| Panel Date: | December 14, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-6 (23.1_PDR_PDP6) meeting. The meeting was chaired by Jim Jordan and conducted via videoconference on December 14, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed
- Panelists: One (1) panel chair, eight (8) expert reviewers, and one (1) advocate reviewer
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Five (5)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: 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.

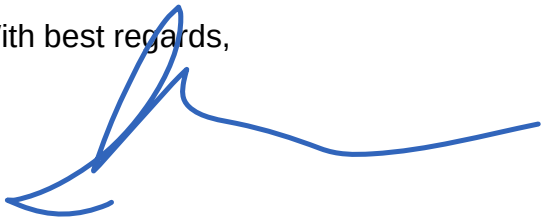
## *CONCLUSION*

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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-7
# (23.1_PDR_PDP7)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-15 23.1_PDR_PDP7 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-7 (23.1 _PDR_PDP7) |
| Panel Date: | December 15, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-7 (23.1_PDR_PDP7) meeting. The meeting was chaired by Alan West and conducted via videoconference on December 15, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) 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: 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 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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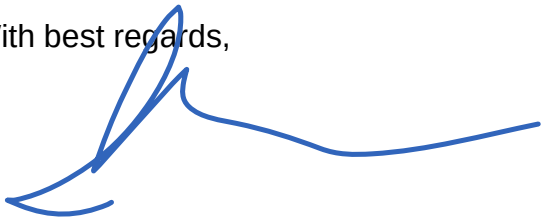
With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-8
# (23.1_PDR_PDP8)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-15 23.1_PDR_PDP8 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-8 (23.1 _PDR_PDP8) |
| Panel Date: | December 15, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-8 (23.1_PDR_PDP8) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on December 15, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

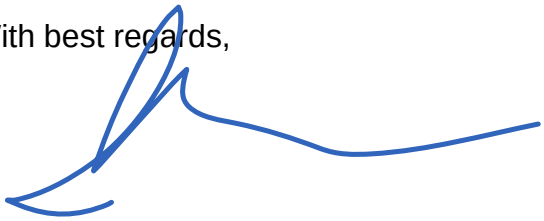
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-9
# (23.1_PDR_PDP9)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-16 23.1_PDR_PDP9 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-9 (23.1 _PDR_PDP9) |
| Panel Date: | December 16, 2022 |
| Report Date: | December 21, 2022 |

## *BACKGROUND*

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

## *INTRODUCTION*

The subject of this report is the 23.1 Product Development Research Panel-9 (23.1_PDR_PDP9) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on December 16, 2022.

## *PANEL OBSERVATION OBJECTIVES AND SCOPE*

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed
- 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

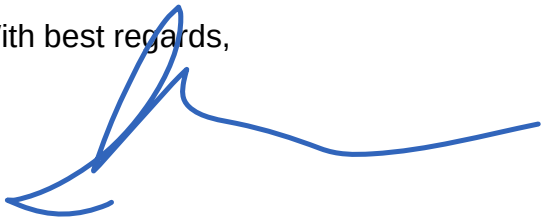
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Research Panel-10
# (23.1_PDR_PDP10)
# Observation Report

| | |
|---|---|
| Report No. | 2022-12-16 23.1_PDR_PDP10 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research Panel-10 (23.1 _PDR_PDP10) |
| Panel Date: | December 16, 2022 |
| Report Date: | December 21, 2022 |

## BACKGROUND

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

## INTRODUCTION

The subject of this report is the 23.1 Product Development Research Panel-10 (23.1_PDR_PDP10) meeting. The meeting was chaired by John McKew and conducted via videoconference on December 16, 2022.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

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

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

## *SUMMARY OF OBSERVATION RESULTS*

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications 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: 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 were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

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

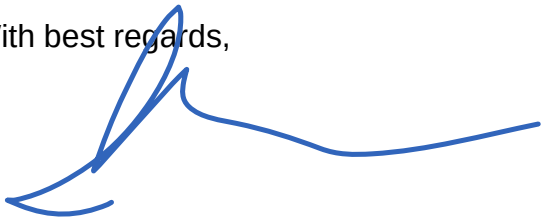
## *CONCLUSION*

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

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

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

With best regards,



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

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Prelimenary Panel-1.16
# (23.1_PDPRE 1.16)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-12 23.1_PDPRE 1.16 |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Prelimenary Panel-1.16 (23.1 _PDPRE 1.16) |
| Panel Date: | January 12, 2023 |
| Report Date: | January 18, 2023 |

## *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 23.1 Product Development Prelimenary Panel-1.16 (23.1_PDPRE 1.16) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on January 12, 2023.

## *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: Three (3) applications were discussed and two (2) applications were not discussed
- Panelists: One (1) panel vice chair, 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: 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.

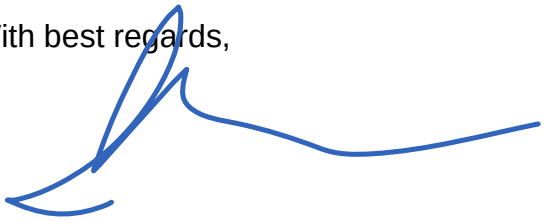
## *CONCLUSION*

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)
# 23.1 Product Development Panel-1 Due Diligence (23.1_PDP-1 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-13 23.1_PDP-1 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-1 Due Diligence (23.1 _PDP-1 DD) |
| Panel Date: | January 13, 2023 |
| Report Date: | January 18, 2023 |

## 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 23.1 Product Development Panel-1 Due Diligence (23.1_PDP-1 DD) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on January 13, 2023.

## 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: 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 (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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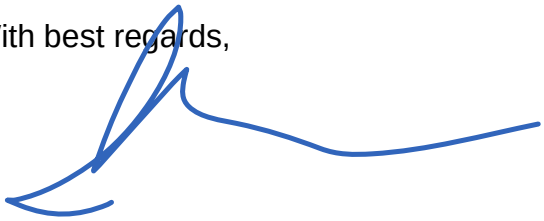
With best regards,



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)
# 23.1 Product Development Panel-9 Due Diligence (23.1_PDP-9 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-13 23.1_PDP-9 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-9 Due Diligence (23.1 _PDP-9 DD) |
| Panel Date: | January 13, 2023 |
| Report Date: | January 18, 2023 |

## *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 23.1 Product Development Panel-9 Due Diligence (23.1_PDP-9 DD) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on January 13, 2023.

## *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
- Due Diligence Consultant Evaluators: Two (2)

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

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

## *CONCLUSION*

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

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

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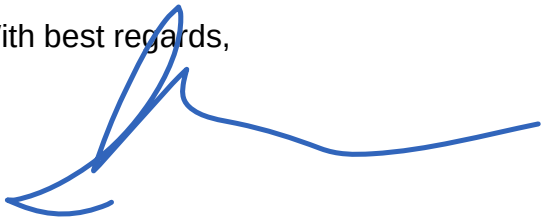

Mara Ash, CIA, CGAP, CGFM, CRMA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

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

# Cancer Prevention and Research Institute of Texas (CPRIT)
# 23.1 Product Development Panel-2 Due Diligence (23.1_PDP-2 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-18 23.1_PDP-2 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-2 Due Diligence (23.1 _PDP-2 DD) |
| Panel Date: | January 18, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-2 Due Diligence (23.1_PDP-2 DD) meeting. The meeting was chaired by Steve Weinstein and conducted via videoconference on January 18, 2023.

## 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: 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.

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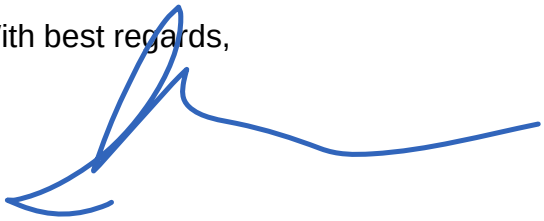
With best regards,



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)
# 23.1 Product Development Panel-8 Due Diligence (23.1_PDP-8 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-18 23.1_PDP-8 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-8 Due Diligence (23.1 _PDP-8 DD) |
| Panel Date: | January 18, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-8 Due Diligence (23.1_PDP-8 DD) meeting. The meeting was chaired by Colin Turnbull and conducted via videoconference on January 18, 2023.

## 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: 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.

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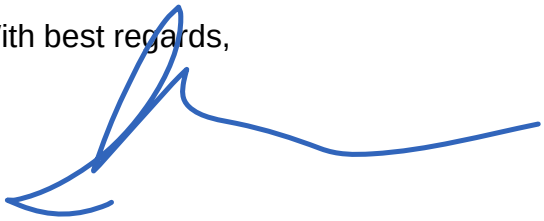
With best regards,



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)
# 23.1 Product Development Panel-5 Due Diligence (23.1_PDP-5 DD)
# Observation Report

| | |
|---|---|
| Report No. | 2023-01-19 23.1_PDP-5 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-5 Due Diligence (23.1 _PDP-5 DD) |
| Panel Date: | January 19, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-5 Due Diligence (23.1_PDP-5 DD) meeting. The meeting was chaired by Bo Saxberg and conducted via videoconference on January 19, 2023.

## 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, eight (8) 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

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.

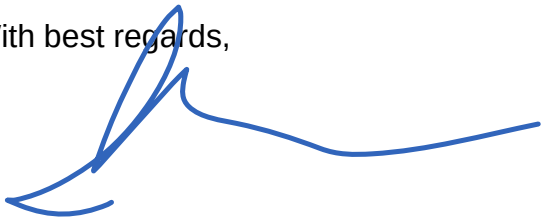
## *CONCLUSION*

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)
# 23.1 Product Development Panel-3 Due Diligence (23.1_PDP-3 DD)
# Observation Report

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| Report No. | 2023-01-20 23.1_PDP-3 DD |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Panel-3 Due Diligence (23.1 _PDP-3 DD) |
| Panel Date: | January 20, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Panel-3 Due Diligence (23.1_PDP-3 DD) meeting. The meeting was chaired by Elaine Jones and conducted via videoconference on January 20, 2023.

## 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 eight (8) 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.

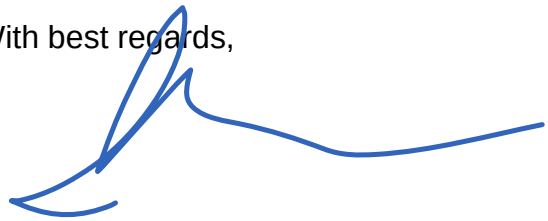
## *CONCLUSION*

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)
# 23.1 Product Development Research - Product Development Review Council Meeting (23.1_PDR-PDRC)
# Observation Report

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|---|---|
| Report No. | 2023-01-23 23.1_PDR-PDRC |
| Program Name: | Product Development Research |
| Panel Name: | 23.1 Product Development Research - Product Development Review Council Meeting (23.1 _PDR-PDRC) |
| Panel Date: | January 23, 2023 |
| Report Date: | January 25, 2023 |

## 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 23.1 Product Development Research - Product Development Review Council Meeting (23.1_PDR-PDRC) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on January 23, 2023.

## PANEL OBSERVATION OBJECTIVES AND SCOPE

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

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

## *SUMMARY OF OBSERVATION RESULTS*

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

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, one (1) panel vice-chair and ten (10) 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: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The COIs did not participate in 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.

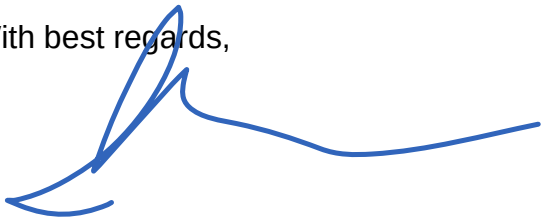
## *CONCLUSION*

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

# Conflicts of Interest Disclosure

## Conflicts of Interest Disclosure

CPRIT Product Development Research Cycle 23.1

Awards Announced at the May 17, 2023, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 23.1 include: *SEED Awards for Product Development Research; Texas New Technologies Company Awards for Product Development Research; Texas Therapeutics Company Awards for Product Development Research* and *Texas Diagnostic and Devices Company Awards for Product Development Research.*

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:** | | | |
| DP230062 | Lewis, Lionel | 7 Hills Pharma LLC | Jones, Elaine |
| DP230066 | Scott, Brenton | Pulmotect, Inc | Geltosky, Jack |
| DP230076 | Stocks, Clifford | OncoResponse | Swiderek, Kristine |
| **Applications not considered by the PIC or Oversight Committee:** | | | |
| DP230031 (preliminary application) | Marija Plodinec | ARTIDIS, Inc | Weinstein, Steve |
| DP230045 (preliminary application) | Carole Spangler Vaughn | Eisana LLC | Swiderek, Kristine |
| DP230015 (preliminary application) | Jason Bock | Resilience Texas LLC dba CTMC | Shoemaker, David |
| DP230093 (preliminary application) | David Arthur | Salarius Pharmaceuticals, Inc. | Jones, Elaine |
| DP230103 | Paola Alvarado | Serene, LLC | Cosan, Roy |

| Application ID | Principal Investigator | Organization | Conflict Noted by Reviewer |
|---|---|---|---|
| (preliminary application) | | | |
| DP230063 (preliminary application) | Mauro Ferrari | BrYet US, Inc. | Canetta, Renzo |

# T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

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|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER |
| **SUBJECT:** | T.A.C. § 702.19 WAIVER |
| **DATE:** | FEBRUARY 1, 2023 |

## 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 six companies that the Product Development Review Council (PDRC) has recommended for grant awards. Doing so 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.

The total budget request for the proposed slate of six companies exceeds the remaining funds allocated for FY 2023 product development program awards. Approving this waiver allows Dr. Smith to negotiate proposed budgets and related goals and objectives with the six companies recommended by the PDRC for product development awards prior to final approval by the Oversight Committee. At its February 1 meeting, the Program Integration Committee (PIC) approved deferring final PIC action on the PDRC's recommendations until the May Oversight Committee meeting. The additional time and this waiver serve our goal of reducing the budget requests by an amount such that CPRIT may fund most or all companies recommended by the PDRC. Granting this 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 2023 product development awards.

# High Level Summary of Due Diligence

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- OmniNano Pharmaceuticals LLC for $2,711,437.

The contract contingencies recommended by the PDRC for this award have been satisfied.

OmniNano Pharmaceuticals LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

OmniNano Pharmaceuticals LLC is a Missouri City-based company which is developing a platform using polymeric micellar nanocarrier to codeliver distinctly different drugs to tumors which thereby increases therapeutic concentrations of individual drugs in a simultaneous manner.

Pancreatic ductal adenocarcinoma (PDAC) has a 5-year survival rate of just 11.5% and an overall median survival time of <1 year with the current standard-of-care treatments. This proposal seeks to develop a polymeric micelle-based solution to PDAC based on a micellar co-formulation delivery platform for cyclopamine (CPA), a naturally-occurring compound capable of depleting cancer stem cells, and paclitaxel (PTX), a cytotoxic chemotherapeutic agent that eliminates proliferating cancer cells. In preclinical studies, the polymeric micelles containing both CPA and PTX, named ONP-001, significantly prolonged the median survival of transgenic KPC mice that harbor certain mutations. In a randomized study, ONP-001 increased median survival of mice by 8-fold compared to nab-paclitaxel and by 7-fold compared to gemcitabine. ONP-001 increased the area of benign pancreatic tissue by 270% and substantially reduced poorly differentiated or moderately differentiated tumor cells.2 The strong anti-PDAC efficacy was achieved with a minimal systemic toxicity. ONP-001 overcomes poor drug delivery of therapeutic agents by continuously remodeling tumor stroma to normalize tumor blood vessels and alleviate tumor hypoxia, which leads to increased ONP-001 delivery via a positive reinforcing feedback loop for delivery efficiency. The goals of the proposed project are to manufacture ONP-001 under current Good Manufacture Practice (cGMP) guidance, to conduct GLP-toxicity and toxicokinetic studies (rodents and non-rodents), and to prepare a robust IND (investigational new drug) package to be filed with the FDA.

**Select Reviewer Comments**

*ONP-01 is an innovative product with potential for effective treatment of PDAC.*

*The management team has experience in managing clinical research projects in nanomedicine, as well as on the development of novel drug-delivery systems for selective delivery of diagnostic and therapeutic agents. The team also includes an expert in pharmacokinetics (PK) and pharmacodynamics (PD) of drug formulations.*

*Strong preclinical data that demonstrate feasibility of clinical approach.*

TNTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Resilience Texas LLC dba CTMC for $9,100,000.

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

Resilience Texas LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Cell Therapy Manufacturing Center (CTMC) is a Houston-based joint venture between National Resilience Inc. and MD Anderson Cancer Center (MDACC) to accelerate cell therapy development. There has been a 10-fold increase in cancer cell therapy trials over the last decade. CTMC focuses on three areas to benefit patients and technology by building capacity and differentiated capabilities for retroviral vector (RVV) manufacturing, tumor infiltrating lymphocyte (TIL) platform improvement, and CAR-T process development strategy.

Autologous cell therapies manufacturing process is fraught with bottlenecks that limit treatment access for many patients due to length of time and high production costs. CTMC's current scientific and structural advantages in autologous cell therapy includes a 60,000 SF facility adjacent to MDACC. The project will provide a vertically integrated approach to 1) accelerate novel therapies to the clinic (reduce time from research to clinical proof of concept) 2) provide a robust strategy to move products from clinical proof of concept to commercialization, and 3) drive down the long-term commercial cost of cellular therapy products.

There are few manufacturing centers that focus on retroviral vectors, and little to no development of downstream process development of the RVV. CTMC will utilize a two-pronged approach: optimized transient transfection to make RVV for a fast-to-clinic strategy as well as development of a robust clonal pools, selected clones, and downstream purification RVV process to support a

streamlined approach for later stage therapies which will provide a reduced overall development timeline.

TIL therapy is a proven and effective option in melanoma, and much of the development of successful manufacturing processes done by the scientific staff that moved from MDACC to CTMC. The project will utilize CTMC's prior expertise in TIL optimization to improve the second phase of the process through final formulation. These improvements will develop a robust and broadly applicable potency assay that is currently lacking in the field, which will open doors for exploration of novel engineering in the TIL field, expansion to additional cancer indications.

Autologous cellular therapies require dedicated equipment, highly trained operators, and individual manufacturing for each patient. CAR-T processes are typically developed solely with healthy donor blood products and standard/unoptimized cryopreservation methods. CTMC proposes to develop scale-down models, accessing and incorporating patient samples during development with quicker and less costly evaluation of automated steps, and by developing data-driven methods for freezing products based on cryopreservation strategies.

The proposal provides that CTMC establish a robust and flexible center for retroviral vector (RVV) manufacturing in Texas; Expand platform expertise by optimizing tumor infiltrating lymphocyte (TIL) manufacturing and provide a differentiated process development approach for CAR-T manufacturing.

**Select Reviewer Comments**

**"***Major strengths of the application include the objectives, which have identified bottle necks in RRV, CAR-T, and TIL manufacturing and propose innovative strategies to overcome them. The close partnership with MD Anderson and a regulatory staff, which allows for essentially 1-stop preclinical to clinical development of cell-based therapeutics, is highly innovative."*

**"***This is a very innovative concept and structure potentially addressing some of the challenges in the cell and gene therapy space … builds permanent jobs in Texas and adds to the needed biotech infrastructure to create a true biotech/oncology ecosystem."*

*"The development plan indicates an opportunity to further research and develop a technology that will save time to get treatment to patients."*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Alterum Therapeutics LLC for $11,721,150.

The contract contingencies recommended by the PDRC for this award have been satisfied.

Allterum Therapeutics LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Allterum Therapeutics LLC is a Houston-based preclinical company formed around research conducted at National Cancer Institute of a monoclonal antibody, 4A10, against CD127 as a treatment for acute lymphoblastic leukemia (ALL). CD127 is a subunit for both the interleukin-7 receptor (IL-7R) and the TSLP receptor, which are expressed on T-Cell ALL and pre-B Cell ALL, respectively. 4A10 binds CD127 and exerts its anticancer activity by a dual mechanism: inhibition of IL-7 signaling and cytotoxicity via ADCC mediated by its IgG1 Fc region. 4A10's anti-cancer activity in ALL has been demonstrated both in vitro and in vivo in multiple labs, including patient-derived xenograft (PDX) models.

There are about 7,000 cases of ALL in the U.S. each year with ~1,600 deaths. ~80% of ALL patients are children, making it the most common childhood cancer in the U.S. ~80% of ALL patients have pre-B cell ALL (B-ALL) and ~20% have T-cell ALL (T-ALL). ALL treatment is a relative success story in cancer. Both B-ALL and T-ALL patients receive a similar first-line regimen, to which ~85% respond. Several options exist for patients with B-ALL who progress after first-line therapy, but a third will still progress or be unable to tolerate available treatments. Patients with T-ALL who progress have an even poorer prognosis, with no approved targeted second-line options. Patients with relapsed or refractory (r/r) ALL have poor outcomes with a 15-35% five-year survival, and are the initial focus of our development.

4A10 is expected to be well tolerated and active even in relapsed disease, it would be attractive to patients who have failed or cannot tolerate other available therapies. The clinical goal of the project is to get a complete response without minimal residue disease making the patient eligible for a potentially curative stem cell transplant. The long-term goal is to expand the label to add 4A10 to standard first-line therapy to increase effectiveness and/or decrease toxicity.

A prior CPRIT Seed award supported scale up 4A10 manufacturing, conduct early toxicological studies, develop clinical protocol, and obtain pre-IND guidance from FDA. 4A10 has received orphan drug and pediatric rare disease designation in ALL. The proposal provides that Allterum will Manufacture of Drug Substance (DS) and Drug Product (DP) under GMP; Perform Pivotal GLP Toxicology Studies to support IND filing; Submit IND and IRB filings and initiate clinical trial site(s) for the Phase I/IIA Clinical Trial of 4A10 in Patients with relapsed/refractory Acute Lymphoblastic Leukemia (r/r ALL); and Conduct First-in-Human Phase I/IIA Clinical Trial for 4A10 in r/r ALL patients.

**Select Reviewer Comments**

*"There is an unmet need for treating recurring or resistant forms of ALL. This applicant is proposing the development of a product to provide benefit to these patients with a low-toxicity product … The applicant has had a pre-IND meeting with the FDA and has incorporated the FDA recommendations into their study design, ie, monotherapy for 28 days. Additionally, the applicant indicates that they have already received orphan drug and pediatric rare disease designation for 4A10 in ALL."*

*"This proposal is very Texas-centric, and the conduct of this work will further both CPRIT's goals and successes."*

*"Novel effective treatment options for relapsed/refractory ALL are needed, and the intended product that targets CD127 could satisfy an unmet need for treatment."*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- 7 Hills Pharma LLC for $13,439,001.

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

7 Hills Pharma LLC

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

7 Hills Pharma LLC is a Houston-based company which is developing 7HP349 which is a first-in-class, oral, small molecule, positive allosteric modulator of integrins critical for immune surveillance (immune cell priming, trafficking and effector functions) that may increase the effectiveness of CPI, with a low risk of elevated immunotoxicities, in PD-1 resistant cancers.

7HP349 as systemic drug has been shown to have single-agent antitumor activity, is synergistic with PD-(L)1, aCTLA-4, and immunogenic doses of radiation with tumor-selective homing of antigen-specific T cells. The priming dose, schedule, and plasma exposures have been defined in multiple mouse tumor and infectious disease models. 7HP349 has been shown not to increase immunotoxicies.

In a Phase I healthy volunteer study, 7HP349 was orally bioavailable with a safety margin of >10x based on the optimal pharmacokinetic (PK) exposures with a minor positive food effect. The single dose and repeat dose PK were non-linear, and the T ½ of ~20h supported once-daily

dosing. 7HP349 doses of 100-300 mg will be dose escalated in combination with ipilimumab and nivolumab.

7 Hills has developed scalable, low-cost manufacturing processes and estimate ambient stability of 5 and 3 years for the 7HP349 Drug Substance (DS) and Product (DP). 16 kg of cGMP DS and 30,000 capsules of DP have been produced and will be ready for clinical use in 2Q2023.

US FDA has granted 7HP349 Orphan Drug designation for treatment of malignant melanoma stages IIB to IV and Fast Track designation for 7HP349 in combination with a CTLA-4 inhibitor for the treatment of patients with unresectable or metastatic *MM* following prior PD-1 inhibitor treatment.

The proposed project aims to establish target-centric patient selection biomarker; manufacture and release of cGMP 7HP349 Drug Product(s) (DP), and complete registrational ICH stability programs; complete the 7HP111, Phase Ib/IIa clinical trial to determine the safety and efficacy of oral 7HP349 in combination with ipilimumab followed by nivolumab in patients with locally advanced or metastatic malignancies (melanoma, HNSCC, NSCLC) resistant to or relapsing after PD-1 inhibitor therapy.

**Select Reviewer Comments**

*"The application states that over 40% of patients with metastatic melanoma are resistant to checkpoint inhibitor therapies. An oral medication that can increase the effectiveness of current immunotherapies without an increase in toxicities would be of benefit to such patients."*

*"7 Hills Pharma is pursuing an unmet medical need with a novel mechanism targeting resistant metastatic melanoma patients with aPD-1 resistance by enhancing ICI effectiveness with 7HP349, a first-in-class, oral, small-molecule, positive allosteric modulator of integrins critical for immune cell priming, T cell trafficking and effector functions."*

*"7 Hills Pharma has presented impressive in vivo pharmacodynamic effects with 7HP349 including significant inhibition of tumor growth and increased response rate in combination with aPD-1 and aCTLA-4 immune checkpoint inhibitors and effected an increase in the recruitment of CD4 and CD8 T cells into the tumor. "*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- Pulmotect Inc. for $8,851,165.

The contract contingencies recommended by the PDRC for this award have been satisfied.

Pulmotect Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Pulmotect, Inc. is a Houston-based company which is developing an immunomodulatory technology to treat and prevent respiratory infections in immunocompromised cancer patients to improve cancer patient outcomes. PUL-042 inhalation solution contains two active ingredients, which act synergistically on Toll-like receptors to stimulate pulmonary epithelial innate immunity and protect against a wide range of pathogens.

Respiratory infections are caused by a variety of pathogenic organisms including viruses, bacteria, and fungi. Cancer patients are highly susceptible to respiratory infection and potentially lethal pneumonia due to suppressed *adaptive* immunity. Pneumonia is second only to the underlying cancer in causing death in cancer patients.

Cancer patients still have intact respiratory epithelium that can respond to stimuli. By stimulating these *innate epithelial immune responses* in the lung and enhancing the ability to fight off invading pathogens, patients can be protected from pulmonary infections, thereby reducing morbidity and mortality. PUL-042, is administered by inhalation and activates the lung epithelial innate defense mechanisms through stimulation of specific lung epithelial Toll-like receptors providing broad protection against invading pathogens. Extensive *in vitro* and *in vivo* preclinical experiments and toxicology studies have demonstrated safety and broad protection against pathogens. PUL-042 has clinical evidence of anti-viral activity against the SARS-CoV-2 virus in a Phase 2 clinical trial. Data in more than 200 PUL-042 treated subjects demonstrate safety and clinical proof of concept thereby increasing the probability of successful development.

Pulmotect proposes to Initiate a Phase 2 Clinical Trial; Complete Patient Enrollment and Complete Final Study Report:

**Select Reviewer Comments**

*Pulmonary infection (pneumonia) among immunocompromised patients is a well established area of unmet clinical need, accounting for the proximate cause of mortality among many hospitalized patients. A "pathogen" agnostic therapeutic modality would have widespread applications.*

*Given the high mortality from pneumonia in immunocompromised cancer patients, the challenges of rapid diagnosis and treatment of one or multiple lung infections and the promise of prophylaxis and/or treatment of viral, bacterial or fungal infections by stimulation of innate immunity in the lung, there is tremendous unmet need and potential for PUL-042.*

TTC Full

High Level Summary of CPRIT Product Development Diligence and Recommendation

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

- OncoResponse for $13,259,174.

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

OncoResponse Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

OncoResponse is a Seattle-based company which is developing OR502 which is a humanized monoclonal antibody for treatment of advanced human malignancies. The target of OR502 is the leukocyte immunoglobulin-like receptor-2/immunoglobulinlike transcript-4 (LILRB2/ILT4) protein which is expressed on the surface of certain immune cells known to play a role in immune response to cancer. OR502 disrupts immuoinhibitory actions of LILRB2, leading to immune stimulation and potentiation of anti-cancer responses.

OR502 is a humanized monoclonal antibody that binds with high affinity and specificity to an epitope on LILRB2 distinct from all other clinical candidates, including MK-4830. OR502 demonstrates specific binding to myeloid cells, no binding to a panel of other immune cells, and potently blocks the interaction of LILRB2 with HLA-G and other HLA-class I molecules. In pre-clinical studies, OR502 demonstrates superior characteristics versus competitors. OR502 outperforms MK-4830 in restoring CD8+ T-cell proliferation, interferon gamma and perforin secretion in M2c/CD8+ T cell coculture assay and rescues interferon gamma production in M2c/Exhausted CD8+ T cell coculture assays. OR502 has 2-pronged functionality, as it reduces the immunosuppressive phenotype of existing tumor associate macrophages (TAMs) and prevents development of new immunosuppressive TAMs.

OncoResponse is developing an OR502-expressing cell line, cell culture process, purification process, analytical methods, and formulation and completed a manufacturability assessment which showing excellent characteristics.

OR502 will be developed for the treatment of solid tumors. The development plan will first determine the safe dose of OR502 in subjects with advanced solid malignancies for which no standard therapies exist, and then evaluate additional safety and potential activity in tumor-specific expansion cohorts. The Phase 1 study will use an efficient dose-escalation design to rapidly determine a safe and potentially efficacious dose and schedule. Concurrent with

monotherapy dose escalation, combination cohorts with an anti-PD-(L)1 will be enrolled to evaluate safety of OR502 in combination.

OncoResponse's proposal provides for completing all IND-enabling studies for OR502 and file NDA with FDA; initiating Phase 1A clinical trials to assess safety and dose level; completing Phase 1A trials and establish RP2D (monotherapy and in combination with anti-PD-1; initiating dose-expansion for 2 indications (monotherapy and in combination); initiating monotherapy biology cohort and conduct additional biomarker analysis and assessing initial ORR for initial patients in expansion and biology cohorts

**Select Reviewer Comments**

*The management team is very strong and experienced, including the CEO who has many years of experience in raising venture capital and mergers and acquisitions. The CMO is a medical oncologist who trained at NIH and has many years of experience in the pharmaceutical industry. The CSO is experienced in biomarker development and generating preclinical data.*

*This is a validated target with potential for addressing important unmet/emerging needs in a variety of cancers.*

*This is a very strong resubmission of an application focused on addressing the unmet need in ICI response.*

# De-Identified Overall Evaluation Scores

# Texas Therapeutics Company Awards for Product Development Research

Product Development Research Cycle 23.1

**Full Application Review**

*One application not recommended for funding has a final score that is more favorable than a recommended application. CPRIT assigns a full application to each individual CPRIT product development review panel to review, score, and decide whether to recommend that application for due diligence review. Cycle 23.1 convened ten peer review panels each made up of seven to ten peer reviewers to review one full application per panel. Only those applications that a review panel judges to be most meritorious will move forward for additional in-depth due diligence.*

| Application ID | Final Overall Score |
|---|---|
| DP230062* | 2.6 |
| DP230071* | 2.6 |
| DP230066* | 3.3 |
| bba | 3.5 |
| DP230076* | 3.6 |
| bbb | 5.3 |
| bbc | 4.6 |

* Recommended for award.

# Texas Therapeutics Company Awards for Product Development Research

Product Development Research Cycle 23.1

*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 | 3.7 |
| Cb | 4.0 |
| Cc | 4.3 |
| Cd | 4.5 |
| Ce | 5.0 |
| Cf | 5.0 |
| Cg | 5.0 |
| Ch | 5.0 |
| Ci | 5.0 |

* Recommended for full application review.

# Final Overall Evaluation Scores and Rank Order Scores

January 30, 2023

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

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

Dr. Patel and Mr. Roberts,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 23.1 grant award cycle. The PDRC convened on January 23, 2023 and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Resilience Texas LLC dba CTMC, Allterum Therapeutics, LLC, 7 Hills Pharma, LLC, Pulmotect, Inc., OmniNano Pharmaceuticals LLC, OncoResponse. The attached table reflects the ranked award recommendation for the six (6) grant applications that CPRIT would like deferred to the May 2023 Oversight Committee meeting.

The PDRC did not make any changes to timelines or budgets for the six (6) projects recommended for funding. However, four (4) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP230071, DP230076, and DP230079 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP230066 related to clinical data and statistical analysis. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

# FY23.1 Product Development Review Council Recommendations

| Ranking | ID | Mechanism | Type | PI Last Name | Application Title | Organization | Score from Due Diligence | Budget |
|---|---|---|---|---|---|---|---|---|
| 1 | DP230079 | TNTC | New | Bock, J | Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value-Added Biotech Partnerships | Resilience Texas LLC dba CTMC | 2.3 | $12,000,000 |
| 2 | DP230062 | TTC | New | Lewis, L | 7HP349, a Small Molecule, Oral Integrin Activator to Treat Patients With anti-PD-1 Resistant Melanoma | 7 Hills Pharma LLC | 2.6 | $18,679,381 |
| 3 | DP230064 | SEED Therapeutics | New | Ma, G | IND-Enabling Studies of ONP-001: A Nano-Codelivery Formulation with Two Drugs of Distinct Mechanisms of Action for Treating Pancreatic Ductal Adenocarcinoma | OmniNano Pharmaceuticals LLC | 3.3 | $2,999,858 |
| 4 | DP230076 | TTC | New | Stocks, C | OncoResponse OR502 anti-LILRB2 monoclonal antibody Phase 1-2 clinical study | OncoResponse | 3.6 | $19,326,953 |
| 5 | DP230066 | TTC | Resubmission | Scott, B | Improving Cancer Patient Outcomes by Activating Lung Innate Immunity | Pulmotect, Inc. | 3.3 | $12,445,092 |
| 6 | DP230071 | TTC | Resubmission | Varadhachary, A | Clinical development of a novel CD127 antibody for treating patients with relapsed/refractory Acute Lymphoblastic Leukemia (ALL) | Allterum Therapeutics, LLC | 2.6 | $17,005,376 |

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application DP230062**
**Texas Therapeutics Company Awards for**
**Product Development Research**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Texas Therapeutics Company Awards for Product Development Research* Request for Applications (RFA). CPRIT received 30 preliminary applications in response to this RFA during cycle 23.1. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 23.1 Product Development Panel-1. 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 overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council (PDRC) Chairman provided the cycle 23.1 recommendation letter to the presiding officers of the PIC and Oversight Committee on January 30, 2023. The PDRC's rank order recommends some of the applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

At their meeting on February 1, 2023, and after a recommendation from the Chief Product Development Officer, the PIC unanimously deferred the six award recommendations made by the PDRC to a future FY2023 meeting date. On May 3, 2023, the PIC unanimously recommended the previously deferred award recommendations to the Oversight Committee.

On February 6, 2023, 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 23.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with the company. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

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."

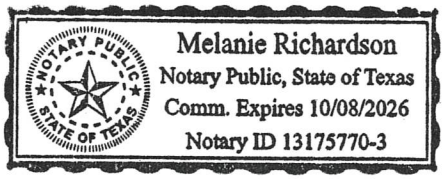
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Melanie Richardson

Melanie Richardson
Notary Public, State of Texas



# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:15 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Product Development
**MECHANISM:** Texas Therapeutics Company Full Awards for Product Development Research
**APPLICATION ID:** DP230062
**APPLICATION TITLE:** 7HP349, a Small Molecule, Oral Integrin Activator to Treat Patients With anti-PD-1 Resistant Melanoma
**APPLICANT NAME:** Lewis, Lionel D
**ORGANIZATION:** 7 Hills Pharma LLC
**PANEL NAME:** 23.1 Product Development Panel-1

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA approved by CPDO** | **08/24/2022** | 01/23/2023 |
| | **RFA approved by CPDO (revised)** | **10/10/2022** | 01/23/2023 |
| | **RFA approved by CPDO (2nd revision)** | **02/01/2023** | 02/01/2023 |
| | **RFA published in Texas.gov eGrants** | **08/25/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System (CARS) opened** | **08/24/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System closed - Cycle 1** | **11/01/2022** | 01/24/2023 |
| | **CPRIT Application Receipt System (CARS) closed** | **01/23/2023** | 01/24/2023 |
| | **Date application submitted** | **10/14/2022** | 01/24/2023 |
| | **Method of submission** | **CARS** | 01/24/2023 |
| | **Within receipt period** | **YES** | 01/24/2023 |
| | **Request for extension to submit application after CARS closed** | **N/A** | 01/24/2023 |
| | **Request for extension for late application submission accepted** | **N/A** | 01/24/2023 |
| | **Submission of application fee** | **YES** | 05/04/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **N/A** | 01/24/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 01/24/2023 |
| | **Assigned to primary reviewers** | **11/10/2022** | 01/24/2023 |
| | **Applicant notified of review panel assignment** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 1 COI signed** | **11/09/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 3 COI signed** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 4 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 5 COI signed** | **11/06/2022** | 01/24/2023 |
| | **Primary Reviewer 6 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 7 COI signed** | **11/05/2022** | 01/24/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 critique submitted** | **11/21/2022** | 01/24/2023 |
| | **Primary Reviewer 3 critique submitted** | **11/26/2022** | 01/24/2023 |
| | **Primary Reviewer 4 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary Reviewer 5 critique submitted** | **11/15/2022** | 01/24/2023 |
| | **Primary Reviewer 6 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary Reviewer 7 critique submitted** | **11/25/2022** | 01/24/2023 |
| | **COI indicated by non-primary reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Peer Review Meeting** | **12/12/2022** | 01/24/2023 |
| | **Post review statements signed** | **12/12/2022** | 01/23/2023 |
| | **Third Party Observer Report** | **12/21/2022** | 01/17/2023 |
| | **Score report delivered to CPDO** | **12/20/2022** | 01/23/2023 |
| | **Recommended for due diligence and IP review** | **YES** | 01/24/2023 |
| **Due Diligence and IP Review** | **Final due diligence review submitted to PDRC** | **01/06/2023** | 03/22/2023 |
| | **Intellectual Property conflict check** | **12/02/2022** | 03/22/2023 |
| | **Final intellectual property review submitted** | **01/06/2023** | 03/22/2023 |
| | **COI indicated by reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Meeting** | **01/13/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/18/2023** | 01/24/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| **Final PDRC Recommendation** | **COI indicated by PDRC member** | **N/A** | 01/24/2023 |
| | **COI indicated by PDRC member** | **Elaine Jones** | 01/24/2023 |
| | **COI recused from participation** | **YES** | 01/24/2023 |
| | **Due Diligence Evaluation Meeting / PDRC Meeting** | **N/A** | 01/23/2023 |
| | **PDRC Meeting** | **01/23/2023** | 01/23/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 02/07/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| | **PDRC Chair Notification to PIC and OC** | **01/30/2023** | 02/07/2023 |
| **PIC Review** | **COI indicated by PIC member** | **N/A** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **02/01/2023** | 05/03/2023 |
| | **Recommended for grant award** | **Other: Deferred** | 05/03/2023 |
| | **COI Indicated by PIC member** | **None** | 05/04/2023 |
| | **COI recused from participation** | **N/A** | 05/04/2023 |
| | **PIC Review Meeting** | **05/03/2023** | 05/04/2023 |
| | **Recommended for grant award** | **YES** | 05/04/2023 |
| **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 | | | |
| **Updated status on 1/18/23 to reflect new review process: Peer Review meeting to Due Diligence meeting.** | | | |

CPRIT maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application DP230064**
**SEED Awards for Product Development Research**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *SEED Awards for Product Development Research* Request for Applications (RFA). CPRIT received 16 preliminary applications in response to this RFA during cycle 23.1, including one preliminary application that was withdrawn. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 23.1 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 overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council (PDRC) Chairman provided the cycle 23.1 recommendation letter to the presiding officers of the PIC and Oversight Committee on January 30, 2023. The PDRC's rank order recommends some of the applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

At their meeting on February 1, 2023, and after a recommendation from the Chief Product Development Officer, the PIC unanimously deferred the six award recommendations made by the PDRC to a future FY2023 meeting date. On May 3, 2023, the PIC unanimously recommended the previously deferred award recommendations to the Oversight Committee.

On February 6, 2023, 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 23.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with the company. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

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."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Melanie Richardson

Melanie Richardson
Notary Public, State of Texas

NOTARY PUBLIC STATE OF TEXAS
Melanie Richardson
Notary Public, State of Texas
Comm. Expires 10/08/2026
Notary ID 13175770-3

# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:15 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Product Development
**MECHANISM:** Seed Full Awards for Product Development Research
**APPLICATION ID:** DP230064
**APPLICATION TITLE:** IND-Enabling Studies of ONP-001: A Nano-Codelivery Formulation with Two Drugs of Distinct Mechanisms of Action for Treating Pancreatic Ductal Adenocarcinoma
**APPLICANT NAME:** Ma, Guorong
**ORGANIZATION:** OmniNano Pharmaceuticals LLC
**PANEL NAME:** 23.1 Product Development Panel-5

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA approved by CPDO** | **08/24/2022** | 01/23/2023 |
| | **RFA approved by CPDO (revised)** | **10/10/2022** | 01/23/2023 |
| | **RFA approved by CPDO (2nd revision)** | **02/01/2023** | 02/01/2023 |
| | **RFA published in Texas.gov eGrants** | **08/25/2022** | 01/24/2023 |
| | **CPRIT Application Receipt System (CARS) opened** | **08/24/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System closed - Cycle 1** | **11/01/2022** | 01/24/2023 |
| | **CPRIT Application Receipt System (CARS) closed** | **01/23/2023** | 01/24/2023 |
| | **Date application submitted** | **10/31/2022** | 01/24/2023 |
| | **Method of submission** | **CARS** | 01/24/2023 |
| | **Within receipt period** | **YES** | 01/24/2023 |
| | **Request for extension to submit application after CARS closed** | **N/A** | 01/24/2023 |
| | **Request for extension for late application submission accepted** | **N/A** | 01/24/2023 |
| | **Submission of application fee** | **YES** | 05/04/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **N/A** | 01/24/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 01/24/2023 |
| | **Assigned to primary reviewers** | **11/09/2022** | 01/24/2023 |
| | **Applicant notified of review panel assignment** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 1 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 3 COI signed** | **11/09/2022** | 01/24/2023 |
| | **Primary Reviewer 4 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 5 COI signed** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 6 COI signed** | **11/05/2022** | 01/24/2023 |
| | **Primary Reviewer 7 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 8 COI signed** | **11/07/2022** | 01/24/2023 |
| | **Primary Reviewer 9 COI signed** | **11/06/2022** | 01/24/2023 |
| | **Primary Reviewer 10 COI signed** | **11/07/2022** | 01/24/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **11/19/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 critique submitted** | **11/21/2022** | 01/24/2023 |
| | **Primary Reviewer 3 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary Reviewer 4 critique submitted** | **11/20/2022** | 01/24/2023 |
| | **Primary Reviewer 5 critique submitted** | **11/28/2022** | 01/24/2023 |
| | **Primary Reviewer 6 critique submitted** | **11/22/2022** | 01/24/2023 |
| | **Primary Reviewer 7 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary Reviewer 8 critique submitted** | **11/15/2022** | 01/24/2023 |
| | **Primary Reviewer 9 critique submitted** | **11/26/2022** | 01/24/2023 |
| | **Primary Reviewer 10 critique submitted** | **11/28/2022** | 01/24/2023 |
| | **COI indicated by non-primary reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Peer Review Meeting** | **12/14/2022** | 01/24/2023 |
| | **Post review statements signed** | **12/14/2022** | 01/24/2023 |
| | **Third Party Observer Report** | **12/21/2022** | 01/17/2023 |
| | **Score report delivered to CPDO** | **12/20/2022** | 01/24/2023 |
| | **Recommended for due diligence and IP review** | **YES** | 01/24/2023 |
| **Due Diligence and IP Review** | **Final due diligence review submitted to PDRC** | **01/06/2023** | 03/22/2023 |
| | **Intellectual Property conflict check** | **12/02/2022** | 03/22/2023 |
| | **Final intellectual property review submitted** | **01/06/2023** | 03/22/2023 |
| | **COI indicated by reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Meeting** | **01/19/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 03/24/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| **Final PDRC Recommendation** | **COI indicated by PDRC member** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Evaluation Meeting / PDRC Meeting** | **N/A** | 01/24/2023 |
| | **PDRC Meeting** | **01/23/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 02/07/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| | **PDRC Chair Notification to PIC and OC** | **01/30/2023** | 02/07/2023 |
| **PIC Review** | **COI indicated by PIC member** | **N/A** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **02/01/2023** | 05/03/2023 |
| | **Recommended for grant award** | **Other: Deferred** | 05/03/2023 |
| | **COI indicated by PIC member** | **None** | 05/04/2023 |
| | **COI recused from participation** | **N/A** | 05/04/2023 |
| | **PIC Review Meeting** | **05/03/2023** | 05/04/2023 |
| | **Recommended for grant award** | **YES** | 05/04/2023 |
| **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 maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application DP230066**
**Texas Therapeutics Company Awards for**
**Product Development Research**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Texas Therapeutics Company Awards for Product Development Research* Request for Applications (RFA). CPRIT received 30 preliminary applications in response to this RFA during cycle 23.1. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 23.1 Product Development Panel-3. 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 overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council (PDRC) Chairman provided the cycle 23.1 recommendation letter to the presiding officers of the PIC and Oversight Committee on January 30, 2023. The PDRC's rank order recommends some of the applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

At their meeting on February 1, 2023, and after a recommendation from the Chief Product Development Officer, the PIC unanimously deferred the six award recommendations made by the PDRC to a future FY2023 meeting date. On May 3, 2023, the PIC unanimously recommended the previously deferred award recommendations to the Oversight Committee.

On February 6, 2023, 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 23.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with the company. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

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."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Melanie Richardson
Notary Public, State of Texas

Melanie Richardson
Notary Public, State of Texas
Comm. Expires 10/08/2026
Notary ID 13175770-3

# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:16 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Product Development
**MECHANISM:** Texas Therapeutics Company Full Awards for Product Development Research
**APPLICATION ID:** DP230066
**APPLICATION TITLE:** Improving Cancer Patient Outcomes by Activating Lung Innate Immunity
**APPLICANT NAME:** Scott, Brenton
**ORGANIZATION:** Pulmotect, Inc.
**PANEL NAME:** 23.1 Product Development Panel-3

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA approved by CPDO** | **08/24/2022** | 01/23/2023 |
| | **RFA approved by CPDO (revised)** | **10/10/2022** | 01/23/2023 |
| | **RFA approved by CPDO (2nd revision)** | **02/01/2023** | 02/01/2023 |
| | **RFA published in Texas.gov eGrants** | **08/25/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System (CARS) opened** | **08/24/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System closed - Cycle 1** | **11/01/2022** | 01/24/2023 |
| | **CPRIT Application Receipt System (CARS) closed** | **01/23/2023** | 01/24/2023 |
| | **Date application submitted** | **10/17/2022** | 01/24/2023 |
| | **Method of submission** | **CARS** | 01/24/2023 |
| | **Within receipt period** | **YES** | 01/24/2023 |
| | **Request for extension to submit application after CARS closed** | **N/A** | 01/24/2023 |
| | **Request for extension for late application submission accepted** | **N/A** | 01/24/2023 |
| | **Submission of application fee** | **YES** | 05/04/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **11/09/2022** | 01/24/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 01/24/2023 |
| | **Assigned to primary reviewers** | **11/09/2022** | 01/24/2023 |
| | **Applicant notified of review panel assignment** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 1 COI signed** | **11/05/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 COI signed** | **11/07/2022** | 01/24/2023 |
| | **Primary Reviewer 3 COI signed** | **11/06/2022** | 01/24/2023 |
| | **Primary Reviewer 4 COI signed** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 5 COI signed** | **11/05/2022** | 01/24/2023 |
| | **Primary Reviewer 6 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 7 COI signed** | **11/06/2022** | 01/24/2023 |
| | **Primary Reviewer 8 COI signed** | **11/05/2022** | 01/24/2023 |
| | **Primary Reviewer 9 COI signed** | **11/07/2022** | 01/24/2023 |
| | **Primary Reviewer 10 COI signed** | **11/06/2022** | 01/24/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **11/21/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 critique submitted** | **12/01/2022** | 01/24/2023 |
| | **Primary Reviewer 3 critique submitted** | **11/28/2022** | 01/24/2023 |
| | **Primary Reviewer 4 critique submitted** | **11/26/2022** | 01/24/2023 |
| | **Primary Reviewer 5 critique submitted** | **11/26/2022** | 01/24/2023 |
| | **Primary Reviewer 6 critique submitted** | **11/25/2022** | 01/24/2023 |
| | **Primary Reviewer 7 critique submitted** | **11/15/2022** | 01/24/2023 |
| | **Primary Reviewer 8 critique submitted** | **11/24/2022** | 01/24/2023 |
| | **Primary Reviewer 9 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary Reviewer 10 critique submitted** | **11/26/2022** | 01/24/2023 |
| | **COI indicated by non-primary reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Peer Review Meeting** | **12/13/2022** | 01/24/2023 |
| | **Post review statements signed** | **12/13/2022** | 01/24/2023 |
| | **Third Party Observer Report** | **12/21/2022** | 01/17/2023 |
| | **Score report delivered to CPDO** | **12/20/2022** | 01/24/2023 |
| | **Recommended for due diligence and IP review** | **YES** | 01/24/2023 |
| **Due Diligence and IP Review** | **Final due diligence review submitted to PDRC** | **01/06/2023** | 03/22/2023 |
| | **Intellectual Property conflict check** | **11/23/2022** | 03/22/2023 |
| | **Final intellectual property review submitted** | **01/17/2023** | 03/22/2023 |
| | **COI indicated by reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Meeting** | **01/20/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 03/24/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| **Final PDRC Recommendation** | **COI indicated by PDRC member** | **N/A** | 01/24/2023 |
| | **COI indicated by PDRC member** | **Jack Geltosky** | 01/24/2023 |
| | **COI recused from participation** | **YES** | 01/24/2023 |
| | **Due Diligence Evaluation Meeting / PDRC Meeting** | **N/A** | 01/24/2023 |
| | **PDRC Meeting** | **01/23/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 02/07/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| | **PDRC Chair Notification to PIC and OC** | **01/30/2023** | 02/07/2023 |
| **PIC Review** | **COI indicated by PIC member** | **N/A** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **02/01/2023** | 05/03/2023 |
| | **Recommended for grant award** | **Other: Deferred** | 05/03/2023 |
| | **COI indicated by PIC member** | **None** | 05/04/2023 |
| | **COI recused from participation** | **N/A** | 05/04/2023 |
| | **PIC Review Meeting** | **05/04/2023** | 05/04/2023 |
| | **Recommended for grant award** | **YES** | 05/04/2023 |
| **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 maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application DP230071**
**Texas Therapeutics Company Awards for**
**Product Development Research**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Texas Therapeutics Company Awards for Product Development Research* Request for Applications (RFA). CPRIT received 30 preliminary applications in response to this RFA during cycle 23.1. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 23.1 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 overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council (PDRC) Chairman provided the cycle 23.1 recommendation letter to the presiding officers of the PIC and Oversight Committee on January 30, 2023. The PDRC's rank order recommends some of the applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

At their meeting on February 1, 2023, and after a recommendation from the Chief Product Development Officer, the PIC unanimously deferred the six award recommendations made by the PDRC to a future FY2023 meeting date. On May 3, 2023, the PIC unanimously recommended the previously deferred award recommendations to the Oversight Committee.

On February 6, 2023, 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 23.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with the company. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

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."

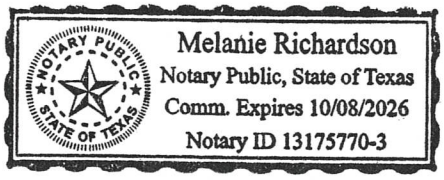
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Melanie Richardson

Melanie Richardson
Notary Public, State of Texas



# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:16 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Product Development
**MECHANISM:** Texas Therapeutics Company Full Awards for Product Development Research
**APPLICATION ID:** DP230071
**APPLICATION TITLE:** Clinical development of a novel CD127 antibody for treating patients with relapsed/refractory Acute Lymphoblastic Leukemia (ALL)
**APPLICANT NAME:** Varadhachary, Atul
**ORGANIZATION:** Allterum Therapeutics, LLC
**PANEL NAME:** 23.1 Product Development Panel-9

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA approved by CPDO** | **08/24/2022** | 01/23/2023 |
| | **RFA approved by CPDO (revised)** | **10/10/2022** | 01/23/2023 |
| | **RFA approved by CPDO (2nd revision)** | **02/01/2023** | 02/01/2023 |
| | **RFA published in Texas.gov eGrants** | **08/25/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System (CARS) opened** | **08/24/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System closed - Cycle 1** | **11/01/2022** | 01/24/2023 |
| | **CPRIT Application Receipt System (CARS) closed** | **01/23/2023** | 01/24/2023 |
| | **Date application submitted** | **10/17/2022** | 01/24/2023 |
| | **Method of submission** | **CARS** | 01/24/2023 |
| | **Within receipt period** | **YES** | 01/24/2023 |
| | **Request for extension to submit application after CARS closed** | **N/A** | 01/24/2023 |
| | **Request for extension for late application submission accepted** | **N/A** | 01/24/2023 |
| | **Submission of application fee** | **YES** | 05/04/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **N/A** | 01/24/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 01/24/2023 |
| | **Assigned to primary reviewers** | **11/10/2022** | 01/24/2023 |
| | **Applicant notified of review panel assignment** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 1 COI signed** | **11/05/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 3 COI signed** | **11/09/2022** | 01/24/2023 |
| | **Primary Reviewer 4 COI signed** | **11/05/2022** | 01/24/2023 |
| | **Primary Reviewer 5 COI signed** | **11/05/2022** | 01/24/2023 |
| | **Primary Reviewer 6 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 7 COI signed** | **11/10/2022** | 01/24/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **11/25/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 critique submitted** | **11/20/2022** | 01/24/2023 |
| | **Primary Reviewer 3 critique submitted** | **11/19/2022** | 01/24/2023 |
| | **Primary Reviewer 4 critique submitted** | **11/17/2022** | 01/24/2023 |
| | **Primary Reviewer 5 critique submitted** | **11/21/2022** | 01/24/2023 |
| | **Primary Reviewer 6 critique submitted** | **11/14/2022** | 01/24/2023 |
| | **Primary Reviewer 7 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **COI indicated by non-primary reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Peer Review Meeting** | **12/16/2022** | 01/24/2023 |
| | **Post review statements signed** | **12/16/2022** | 01/24/2023 |
| | **Third Party Observer Report** | **12/21/2022** | 01/17/2023 |
| | **Score report delivered to CPDO** | **12/20/2022** | 01/24/2023 |
| | **Recommended for due diligence and IP review** | **YES** | 01/24/2023 |
| **Due Diligence and IP Review** | **Final due diligence review submitted to PDRC** | **01/06/2023** | 03/22/2023 |
| | **Intellectual Property conflict check** | **12/02/2022** | 03/22/2023 |
| | **Final intellectual property review submitted** | **01/09/2023** | 03/22/2023 |
| | **COI indicated by reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Meeting** | **01/13/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/18/2023** | 01/24/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| **Final PDRC Recommendation** | **COI indicated by PDRC member** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Evaluation Meeting / PDRC Meeting** | **N/A** | 01/24/2023 |
| | **PDRC Meeting** | **01/23/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 02/07/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| | **PDRC Chair Notification to PIC and OC** | **01/30/2023** | 02/07/2023 |
| **PIC Review** | **COI indicated by PIC member** | **N/A** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **02/01/2023** | 05/03/2023 |
| | **Recommended for grant award** | **Other: Deferred** | 05/03/2023 |
| | **COI indicated by PIC member** | **None** | 05/04/2023 |
| | **COI recused from participation** | **N/A** | 05/04/2023 |
| | **PIC Review Meeting** | **05/03/2023** | 05/04/2023 |
| | **Recommended for grant award** | **YES** | 05/04/2023 |
| **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 maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application DP230076**
**Texas Therapeutics Company Awards for**
**Product Development Research**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Texas Therapeutics Company Awards for Product Development Research* Request for Applications (RFA). CPRIT received 30 preliminary applications in response to this RFA during cycle 23.1. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 23.1 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 overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council (PDRC) Chairman provided the cycle 23.1 recommendation letter to the presiding officers of the PIC and Oversight Committee on January 30, 2023. The PDRC's rank order recommends some of the applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

At their meeting on February 1, 2023, and after a recommendation from the Chief Product Development Officer, the PIC unanimously deferred the six award recommendations made by the PDRC to a future FY2023 meeting date. On May 3, 2023, the PIC unanimously recommended the previously deferred award recommendations to the Oversight Committee.

On February 6, 2023, 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 23.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with the company. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

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."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Melanie Richardson

Melanie Richardson
Notary Public, State of Texas

NOTARY PUBLIC STATE OF TEXAS
Melanie Richardson
Notary Public, State of Texas
Comm. Expires 10/08/2026
Notary ID 13175770-3

# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:16 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Product Development
**MECHANISM:** Texas Therapeutics Company Full Awards for Product Development Research
**APPLICATION ID:** DP230076
**APPLICATION TITLE:** OncoResponse OR502 anti-LILRB2 monoclonal antibody Phase 1-2 clinical study
**APPLICANT NAME:** Stocks, Clifford J
**ORGANIZATION:** OncoResponse
**PANEL NAME:** 23.1 Product Development Panel-8

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA approved by CPDO** | **08/24/2022** | 01/23/2023 |
| | **RFA approved by CPDO (revised)** | **10/10/2022** | 01/23/2023 |
| | **RFA approved by CPDO (2nd revision)** | **02/01/2023** | 02/01/2023 |
| | **RFA published in Texas.gov eGrants** | **08/25/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System (CARS) opened** | **08/24/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System closed - Cycle 1** | **11/01/2022** | 01/24/2023 |
| | **CPRIT Application Receipt System (CARS) closed** | **01/23/2023** | 01/24/2023 |
| | **Date application submitted** | **10/18/2022** | 01/24/2023 |
| | **Method of submission** | **CARS** | 01/24/2023 |
| | **Within receipt period** | **YES** | 01/24/2023 |
| | **Request for extension to submit application after CARS closed** | **N/A** | 01/24/2023 |
| | **Request for extension for late application submission accepted** | **N/A** | 01/24/2023 |
| | **Submission of application fee** | **YES** | 05/04/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **N/A** | 01/24/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 01/24/2023 |
| | **Assigned to primary reviewers** | **11/10/2022** | 01/24/2023 |
| | **Applicant notified of review panel assignment** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 1 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 3 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 4 COI signed** | **11/10/2022** | 01/24/2023 |
| | **Primary Reviewer 5 COI signed** | **11/09/2022** | 01/24/2023 |
| | **Primary Reviewer 6 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 7 COI signed** | **11/06/2022** | 01/24/2023 |
| | **Primary Reviewer 8 COI signed** | **11/04/2022** | 01/24/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **11/20/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 critique submitted** | **11/26/2022** | 01/24/2023 |
| | **Primary Reviewer 3 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary Reviewer 4 critique submitted** | **11/29/2022** | 01/24/2023 |
| | **Primary Reviewer 5 critique submitted** | **11/25/2022** | 01/24/2023 |
| | **Primary Reviewer 6 critique submitted** | **12/01/2022** | 01/24/2023 |
| | **Primary Reviewer 7 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary Reviewer 8 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **COI indicated by non-primary reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Peer Review Meeting** | **12/15/2022** | 01/24/2023 |
| | **Post review statements signed** | **12/16/2022** | 01/24/2023 |
| | **Third Party Observer Report** | **12/21/2022** | 01/17/2023 |
| | **Score report delivered to CPDO** | **12/20/2022** | 01/24/2023 |
| | **Recommended for due diligence and IP review** | **YES** | 01/24/2023 |
| **Due Diligence and IP Review** | **Final due diligence review submitted to PDRC** | **01/06/2023** | 03/22/2023 |
| | **Intellectual Property conflict check** | **12/02/2022** | 03/22/2023 |
| | **Final intellectual property review submitted** | **01/06/2023** | 03/22/2023 |
| | **COI indicated by reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Meeting** | **01/18/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 05/03/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| **Final PDRC Recommendation** | **COI indicated by PDRC member** | **N/A** | 01/24/2023 |
| | **COI indicated by PDRC member** | **Kristine Swiderek** | 01/24/2023 |
| | **COI recused from participation** | **YES** | 01/24/2023 |
| | **Due Diligence Evaluation Meeting / PDRC Meeting** | **N/A** | 01/24/2023 |
| | **PDRC Meeting** | **01/23/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 02/07/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| | **PDRC Chair Notification to PIC and OC** | **01/30/2023** | 02/07/2023 |
| **PIC Review** | **COI indicated by PIC member** | **N/A** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **02/01/2023** | 05/03/2023 |
| | **Recommended for grant award** | **Other: Deferred** | 05/03/2023 |
| | **COI indicated by PIC member** | **None** | 05/04/2023 |
| | **COI recused from participation** | **N/A** | 05/04/2023 |
| | **PIC Review Meeting** | **05/03/2023** | 05/04/2023 |
| | **Recommended for grant award** | **YES** | 05/04/2023 |
| **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 maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**CEO AFFIDAVIT**
**Application DP230079**
**Texas New Technologies Company Awards for**
**Product Development Research**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Texas New Technologies Company Awards for Product Development Research* Request for Applications (RFA). CPRIT received eight preliminary applications in response to this RFA during cycle 23.1, including one preliminary application that was withdrawn. The preliminary review panel recommended this application for full application review and CPRIT subsequently assigned the full application to 23.1 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 overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council (PDRC) Chairman provided the cycle 23.1 recommendation letter to the presiding officers of the PIC and Oversight Committee on January 30, 2023. The PDRC's rank order recommends some of the applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.

At their meeting on February 1, 2023, and after a recommendation from the Chief Product Development Officer, the PIC unanimously deferred the six award recommendations made by the PDRC to a future FY2023 meeting date. On May 3, 2023, the PIC unanimously recommended the previously deferred award recommendations to the Oversight Committee.

On February 6, 2023, 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 23.1 grant applicants, pursuant to Texas Administrative Code § 702.19(e). The waiver allowed Dr. Smith to negotiate a budget reduction with the company. A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

Tracey Davies, CPRIT's Chief Strategic Initiatives and Intellectual Property Officer, performed the intellectual property due diligence review for this grant application. CPRIT has contracts with two outside counsel law firms to perform intellectual property review; however, both law firms reported conflicts of interest that prevented them from reviewing this application. Dr. Ken Smith was unable to conduct due diligence review because he is CPRIT's Chief Product Development Officer and a voting member of the PIC. Ms. Davies previously performed due diligence for CPRIT as outside counsel and reported no conflict of interest with this application. She does not vote or otherwise take any role in recommending awards to the Oversight Committee.

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.

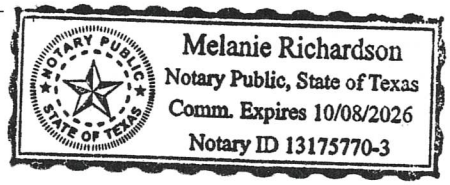
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 4 day of May, 2023, by WAYNE R. ROBERTS.

Melanie Richardson
Notary Public, State of Texas



# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# APPLICATION PEDIGREE

### Date and time exported: 05/04/2023 04:16 PM CT

**FY:** 2023
**CYCLE:** 1
**PROGRAM:** Product Development
**MECHANISM:** Texas New Technologies Company Full Awards for Product Development Research
**APPLICATION ID:** DP230079
**APPLICATION TITLE:** Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value- Added Biotech Partnerships
**APPLICANT NAME:** Bock, Jason
**ORGANIZATION:** Resilience Texas LLC dba CTMC
**PANEL NAME:** 23.1 Product Development Panel-2

| Category | Compliance Requirement | Information | Attestation Date |
|---|---|---|---|
| **Pre-Receipt** | **RFA approved by CPDO** | **08/24/2022** | 01/23/2023 |
| | **RFA approved by CPDO (revised)** | **10/10/2022** | 01/23/2023 |
| | **RFA approved by CPDO (2nd revision)** | **02/01/2023** | 02/01/2023 |
| | **RFA published in Texas.gov eGrants** | **08/25/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System (CARS) opened** | **08/24/2022** | 01/23/2023 |
| | **CPRIT Application Receipt System closed - Cycle 1** | **11/01/2022** | 01/24/2023 |
| | **CPRIT Application Receipt System (CARS) closed** | **01/23/2023** | 01/24/2023 |
| | **Date application submitted** | **10/23/2022** | 01/24/2023 |
| | **Method of submission** | **CARS** | 01/24/2023 |
| | **Within receipt period** | **YES** | 01/24/2023 |
| | **Request for extension to submit application after CARS closed** | **N/A** | 01/24/2023 |
| | **Request for extension for late application submission accepted** | **N/A** | 01/24/2023 |
| | **Submission of application fee** | **YES** | 05/04/2023 |
| **Receipt, Referral, and Assignment** | **Administrative review notification** | **N/A** | 01/24/2023 |
| | **Donation(s) made to CPRIT / foundation** | **NO** | 01/24/2023 |
| | **Assigned to primary reviewers** | **11/10/2022** | 01/24/2023 |
| | **Applicant notified of review panel assignment** | **11/08/2022** | 01/24/2023 |
| | **Primary Reviewer 1 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 3 COI signed** | **11/07/2022** | 01/24/2023 |
| | **Primary Reviewer 4 COI signed** | **11/04/2022** | 01/24/2023 |
| | **Primary Reviewer 5 COI signed** | **11/05/2022** | 01/24/2023 |
| | **Primary Reviewer 6 COI signed** | **11/10/2022** | 01/24/2023 |
| | **Primary Reviewer 7 COI signed** | **11/06/2022** | 01/24/2023 |
| **Peer Review Meeting** | **Primary Reviewer 1 critique submitted** | **11/21/2022** | 01/24/2023 |
| | **Primary (Advocate) Reviewer 2 critique submitted** | **11/18/2022** | 01/24/2023 |
| | **Primary Reviewer 3 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **Primary Reviewer 4 critique submitted** | **12/05/2022** | 01/24/2023 |
| | **Primary Reviewer 5 critique submitted** | **11/26/2022** | 01/24/2023 |
| | **Primary Reviewer 6 critique submitted** | **11/29/2022** | 01/24/2023 |
| | **Primary Reviewer 7 critique submitted** | **11/27/2022** | 01/24/2023 |
| | **COI indicated by non-primary reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Peer Review Meeting** | **12/12/2022** | 01/24/2023 |
| | **Post review statements signed** | **12/12/2022** | 01/24/2023 |
| | **Third Party Observer Report** | **12/21/2022** | 01/17/2023 |
| | **Score report delivered to CPDO** | **12/20/2022** | 01/24/2023 |
| | **Recommended for due diligence and IP review** | **YES** | 01/24/2023 |
| **Due Diligence and IP Review** | **Final due diligence review submitted to PDRC** | **01/06/2023** | 04/24/2023 |
| | **Intellectual Property conflict check** | **11/23/2022** | 04/27/2023 |
| | **Intellectual Property conflict check** | **12/02/2022** | 04/27/2023 |
| | **Final intellectual property review submitted** | **01/13/2023** | 04/24/2023 |
| | **COI indicated by reviewer** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Meeting** | **01/18/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 03/24/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| **Final PDRC Recommendation** | **COI indicated by PDRC member** | **NONE** | 01/24/2023 |
| | **COI recused from participation** | **N/A** | 01/24/2023 |
| | **Due Diligence Evaluation Meeting / PDRC Meeting** | **N/A** | 01/24/2023 |
| | **PDRC Meeting** | **01/23/2023** | 01/24/2023 |
| | **Third Party Observer Report** | **01/25/2023** | 02/07/2023 |
| | **Recommended for grant award** | **YES** | 01/24/2023 |
| | **PDRC Chair Notification to PIC and OC** | **01/30/2023** | 02/07/2023 |
| **PIC Review** | **COI indicated by PIC member** | **N/A** | 05/03/2023 |
| | **COI recused from participation** | **N/A** | 05/03/2023 |
| | **PIC Review Meeting** | **02/01/2023** | 05/03/2023 |
| | **Recommended for grant award** | **Other: Deferred** | 05/03/2023 |
| | **COI indicated by PIC member** | **None** | 05/04/2023 |
| | **COI recused from participation** | **N/A** | 05/04/2023 |
| | **PIC Review Meeting** | **05/03/2023** | 05/04/2023 |
| | **Recommended for grant award** | **YES** | 05/04/2023 |
| **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 | | | |
| **Updated status on 1/18/23 to reflect new review process: Peer Review meeting to Due Diligence meeting.** | | | |

CPRIT maintains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

May 5, 2023

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendation for funding nine grant applications totaling $73,081,927. The PIC recommendations for three academic research and six product development research grant awards are attached.

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

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

The award recommendations will not be considered final until the Oversight Committee meeting on May 17, 2023. Consistent with the non-disclosure agreement that all Oversight Committee members have signed, the recommendations should be kept confidential and not be disclosed to anyone until the award list is publicly announced at the Oversight Committee meeting. I request that Oversight Committee members not print, email, or save to your computer's hard drive any material on the portal. I appreciate your assistance in taking all necessary precautions to protect this information.

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

Thank you for being part of this endeavor.

Sincerely,
Wayne R. Roberts,
Chief Executive Officer

## ACADEMIC RESEARCH GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of three academic research recruitment grant proposals totaling $14,000,000. The recommended grant proposals were submitted in response to the following grant mechanisms: *Recrutiment of Established Investigators*; and *Recruitment of First-Time, Tenure-Track Faculty Members.*

The Scientific Review Council (SRC) provided the prioritized list of four recommendations for grant awards to the presiding officers on April 14, 2023. Prior to the PIC meeting, one of the recommended applications was withdrawn by the applicant; therefore, the PIC considered three recruitment recommendations at its May 3 meeting.

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

- Could lead to immediate or long-term medical and scientific breakthroughs in the area of Cancer Prevention or cures for cancer;
- Strengthen and enhance fundamental science in Cancer Research;
- Ensure a comprehensive coordinated approach to Cancer Research and Cancer Prevention;
- Address federal or other major research sponsors' priorities in emerging scientific or Technology fields in the area of Cancer Prevention, or cures for cancer
- Have a demonstrable economic development benefit to this state;
- Enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources; and
- Address the goals of the Texas Cancer Plan.

**Academic Research Recruitment Award Recommendations**
**Cycle 23.4**

*REI: Recruitment of Established Investigators*
*RFTFM: Recruitment of First-Time, Tenure-Track Faculty Members*

| Rank | App. ID | Mechanism | Candidate | Organization | Budget | Final Score |
|---|---|---|---|---|---|---|
| 1 | RR230031 | RFTFM | Dian Yang, Ph.D. | The University of Texas Southwestern Medical Center | $2,000,000 | 1.0 |

| Academic Research Recruitment Award Recommendations<br>Cycle 23.4<br>*REI: Recruitment of Established Investigators*<br>*RFTFM: Recruitment of First-Time, Tenure-Track Faculty Members* | | | | | | |
|---|---|---|---|---|---|---|
| **Rank** | **App. ID** | **Mechanism** | **Candidate** | **Organization** | **Budget** | **Final Score** |
| 2 | RR230032 | REI | Yuan Zhu, M.D. | The University of Texas Southwestern Medical Center | $6,000,000 | 1.8 |
| 3 | RR230029 | REI | Michael King, Ph.D. | Rice University | $6,000,000 | 2.0 |

## PRODUCT DEVELOPMENT RESEARCH GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of six product development research grant proposals totaling $59,081,927. The recommended grant proposals were submitted in response to the following grant mechanisms: *SEED Awards for Product Development Research; Texas New Technologies Company Awards for Product Development Research;* and *Texas Therapeutics Company Awards for Product Development Research*.

The Product Development Review Council (PDRC) provided the prioritized list of recommendations to the presiding officers on January 30, 2023. The PIC deferred the six recommended awards at its February 1 meeting to allow time for the Chief Product Development Officer to negotiate budget reductions with each of the six companies. I notified the Oversight Committee on February 6, 2023, that pursuant to Texas Administrative Code § 702.19(e) I granted Dr. Smith a waiver from the general prohibition against communicating to allow him to conduct the budget negotiations. The PIC unanimously recommended the previously deferred applications with revised budgets at its May 3 meeting.

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;
- Ensure a comprehensive coordinated approach to cancer research;
- 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;
- 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 Award Recommendations**
**Cycle 23.1**

*SEED: SEED Awards for Product Development Research*
*TNTC: Texas New Technologies Company Awards for Product Development Research*
*TTC: Texas Therapeutics Company Awards for Product Development Research*

| Rank | App. ID | Mechanism | Application Title | PI | Organization | Budget | Final Score |
|---|---|---|---|---|---|---|---|
| 1 | DP230079 | TNTC | Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value-Added Biotech Partnerships | Bock, Jason | Resilience Texas LLC dba CTMC | $9,100,000 | 2.3 |
| 2 | DP230062 | TTC | 7HP349, a Small Molecule, Oral lntegrin Activator to Treat Patients With anti-P0-1 Resistant Melanoma | Lewis, Lionel D | 7 Hills Pharma LLC | $13,439,001 | 2.6 |

**Product Development Research Award Recommendations**
**Cycle 23.1**

*SEED: SEED Awards for Product Development Research*
*TNTC: Texas New Technologies Company Awards for Product Development Research*
*TTC: Texas Therapeutics Company Awards for Product Development Research*

| Rank | App. ID | Mechanism | Application Title | PI | Organization | Budget | Final Score |
|---|---|---|---|---|---|---|---|
| 3 | DP230064 | SEED | IND-Enabling Studies of ONP-001: A Nano-Codelivery Formulation with Two Drugs of Distinct Mechanisms of Action for Treating Pancreatic Ductal Adenocarcinoma | Ma, Guorong | OmniNano Pharmaceuticals LLC | $2,711,437 | 3.3 |
| 4 | DP230076 | TTC | OncoResponse OR502 anti-LILRB2 monoclonal antibody Phase 1-2 clinical study | Stocks, Clifford J | OncoResponse | $13,259,174 | 3.6 |
| 5 | DP230066 | TTC | Improving Cancer Patient Outcomes by Activating Lung Innate Immunity | Scott, Brenton | Pulmotect, Inc. | $8,851,165 | 3.3 |
| 6 | DP230071 | TTC | Clinical development of a novel CD127 antibody for treating patients with relapsed/refractory Acute Lymphoblastic Leukemia (ALL) | Varadhachary, Atul | Allterum Therapeutics, LLC | $11,721,150 | 2.6 |

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

February 3, 2023

Dear Oversight Committee Members:

Pursuant to Tex. Admin. Code § 703.7(d), this letter serves as notification of the list of grant applications deferred by the PIC. At their meeting on February 1, members of the PIC unanimously agreed to defer 25 Academic Research and six Product Development Research grant application recommendations from the Scientific Review Council (SRC) and Product Development Review Council (PDRC), respectively. The attached tables list the application ID, grant mechanism, and institution of each deferred grant application.

Dr. Michelle Le Beau, CPRIT's Chief Scientific Officer, and Dr. Ken Smith, CPRIT's Chief Product Development Officer, recommended deferral of the 31 grant applications because of budget constraints for the remainder of FY2023. Both the SRC's and PDRC's recommendations exceeded the amount of agency funds available for each program. To reduce the funding amount recommended to the Oversight Committee, Dr. Le Beau suggested deferring 25 academic research applications that scored 2.8 or higher during peer review. Dr. Smith recommended deferring the six product development recommendations to allow him time to negotiate budget reductions with the companies.

The PIC may consider and recommend the deferred applications at a future FY2023 meeting. No Oversight Committee action is necessary at this time.

Sincerely,
Wayne R. Roberts
Chief Executive Officer

Table 1. Deferred Academic Research Grant Applications

| **Deferred Academic Research Grant Applications**<br>*IIRA: Individual Investigator Research Awards*<br>*IIRACCA: Individual Investigator Research Awards for Cancer in Children and Adolescents*<br>*IIRACSBC: Individual Investigator Research Awards for Computational Systems Biology of Cancer*<br>*IIRACT: Individual Investigator Research Awards for Clinical Translation* | | |
|---|---|---|
| **Application ID** | **Mechanism** | **Institution** |
| RP230012 | IIRA | Texas Tech University Health Sciences Center at El Paso |
| RP230019 | IIRA | Baylor College of Medicine |
| RP230071 | IIRA | The University of Texas Southwestern Medical Center |
| RP230112 | IIRA | The University of Texas M. D. Anderson Cancer Center |
| RP230134 | IIRACSBC | The University of Texas M. D. Anderson Cancer Center |
| RP230143 | IIRACCA | The University of Texas M. D. Anderson Cancer Center |
| RP230161 | IIRACT | The University of Texas Southwestern Medical Center |
| RP230162 | IIRACCA | The University of Texas Health Science Center at San Antonio |
| RP230174 | IIRACCA | The University of Texas at Austin |
| RP230181 | IIRA | The University of Texas M. D. Anderson Cancer Center |
| RP230184 | IIRA | The University of Texas Southwestern Medical Center |
| RP230196 | IIRA | Baylor College of Medicine |
| RP230197 | IIRA | Baylor College of Medicine |
| RP230216 | IIRA | The University of Texas Southwestern Medical Center |
| RP230240 | IIRA | Baylor College of Medicine |
| RP230241 | IIRA | Baylor College of Medicine |
| RP230272 | IIRA | The University of Texas Southwestern Medical Center |
| RP230283 | IIRA | The University of Texas M. D. Anderson Cancer Center |

| **Deferred Academic Research Grant Applications**<br>*IIRA: Individual Investigator Research Awards*<br>*IIRACCA: Individual Investigator Research Awards for Cancer in Children and Adolescents*<br>*IIRACSBC: Individual Investigator Research Awards for Computational Systems Biology of Cancer*<br>*IIRACT: Individual Investigator Research Awards for Clinical Translation* | | |
|---|---|---|
| **Application ID** | **Mechanism** | **Institution** |
| RP230307 | IIRA | The University of Texas M. D. Anderson Cancer Center |
| RP230319 | IIRACSBC | Baylor College of Medicine |
| RP230323 | IIRA | The University of Texas at Dallas |
| RP230327 | IIRA | The University of Texas Southwestern Medical Center |
| RP230333 | IIRA | Rice University |
| RP230375 | IIRA | The University of Texas Health Science Center at Houston |
| RP230381 | IIRA | The University of Texas Southwestern Medical Center |

Table 2. Deferred Product Development Research Grant Applications

| **Deferred Product Development Research Grant Applications**<br>*SEED: SEED Awards for Product Development Research*<br>*TNTC: Texas New Technologies Company Awards for Product Development Research*<br>*TTC: Texas Therapeutics Company Awards for Product Development Research* | | |
|---|---|---|
| **Application ID** | **Mechanism** | **Company** |
| DP230062 | TTC | 7 Hills Pharma LLC |
| DP230064 | SEED Therapeutics | OmniNano Pharmaceuticals LLC |
| DP230066 | TTC | Pulmotect, Inc. |
| DP230071 | TTC | Allterum Therapeutics, LLC |
| DP230076 | TTC | OncoResponse |
| DP230079 | TNTC | Resilience Texas LLC dba CTMC |

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | VINCE BURGESS, CHIEF COMPLIANCE OFFICER |
| **SUBJECT:** | COMPLIANCE CERTIFICATION – MAY 2023 AWARDS |
| **DATE:** | MAY 4, 2023 |

**Summary and Recommendation:**

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

- Recruitment of Established Investigators
- Recruitment of First-Time Tenure Track Faculty Members
- Texas Therapeutics Company Awards
- Texas New Technologies Company Awards
- Seed Awards for Product Development Research

The following mechanism also received applications during this award cycle; however, did not result in recommendations to the Oversight Committee for its May 17, 2023, meeting: Texas Device and Diagnostics Company Awards.

I have conferred with staff at CPRIT and General Dynamics Information Technology (GDIT), CPRIT's contracted third-party grants administrator, regarding the academic research and product development research 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 and product development research 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 CPRIT's Application Receipt System (CARS) are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to

CPRIT (through the CPRIT Helpdesk that is managed by GDIT) to allow for a submission after the deadline. The program officer considers any requests for extension and may approve an extension for good cause. When a late filing request is approved, the applicant is notified, and CARS is reopened for a brief period – usually two to three hours – the next business day.

*Academic Research:*

*For recruitment cycle 23.4, four applications were received for the Recruitment of Established Investigators RFA and three 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 product development cycle 23.1, CPRIT uploaded the RFAs on the Texas.gov eGrants website. For Cycle 23.1, 30 preliminary applications for the Texas Therapeutics Company (TTC) Product Development Awards RFA, six preliminary applications were received for the Texas Devices and Diagnostics Company (TDDC) Product Development Research Awards RFA, eight preliminary applications were received for the Texas New Technologies Company (TNTC) Product Development Research Awards RFA and 16 preliminary applications were received for the Seed Awards for Product Development Research RFA.*

*After preliminary review, CPRIT issued invitations to submit full applications to 29 applicants (21 TTC applicants, one TDDC applicant, two TNTC applicants, and five Seed Company applicants). Fourteen invited applicants (nine TTC applicants, one TDDC applicant, two TNTC applicants, and one Seed Company applicant) submitted full applications by the November 1, 2022, deadline for cycle 23.1. However, CPRIT notified applicants in October that due to time and resource constraints CPRIT would review only the first ten applicants as determined by the time/date submitted to CARS. CPRIT reviewed full applications submitted by seven TTC applicants, two TNTC applicants, and one Seed Company applicant. CPRIT deferred to a future review cycle four full applications submitted by the November 1, 2022, cycle 23.1 deadline that were not among the first ten applicants received as determined by submission time/date.*

*All preliminary and full applications were submitted through CARS. No applicants requested an extension to submit an application after the deadline.*

**Receipt, Referral, and Assignment Compliance:**

Once applications have been submitted through CARS, GDIT staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, GDIT notifies the program officer, and the program officer makes the final decision whether to administratively

withdraw the application. Recruitment grant applications are assigned to the Scientific Review Council members for peer review. 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 23.4, one recruitment application was withdrawn by the applicant after they were recommended by the Scientific Review Council (SRC) but prior to the PIC meeting.*

*Product Development Research:*

*CPRIT withdrew a TNTC application and a Seed Company application without review due to the closing of the application portal for the fiscal year.*

**Peer Review:**

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

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

*Academic Research:*

*For the Recruitment Awards, the applications are reviewed by the Scientific Review Council (SRC), which assigns two members of the SRC to be primary reviewers. I reviewed the supporting documentation, such as the sign-out sheets, third-party observer reports, and post-review peer reviewer statements. Sign out sheets are used to document when a reviewer with a conflict of interest*

*associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application. Two conflicts of interest were declared by the SRC for recruitment cycle 23.4.*

*I reviewed and confirmed that the post review conflict of interest statements were signed by the six reviewers that attended the Recruitment Review Panel meeting on March 16, 2023.*

*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 review while intellectual property review is conducted by CPRIT's outside counsel. For cycle 23.1, CPRIT's Chief Strategic Initiatives and Intellectual Property Officer conducted the intellectual property review of one grant application because both outside counsel firms under contract with CPRIT reported a conflict of interest with the applicant. 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 12 PDRC members that attended the meeting on January 23, 2023, to determine the final slate of recommended awards.*

**Programmatic Review:**

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

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

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

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

*Academic Research:*

*The SRC met on March 16, 2023, to consider seven applications. After review and discussion of these applications, the SRC recommended four applications to the Program Integration Committee (PIC) for consideration. Because recruitment applications are assigned to the SRC, programmatic and peer review occur simultaneously when applications are reviewed by the SRC.*

*For cycle 23.4, one recruitment application was withdrawn by the applicant after they were recommended by the Scientific Review Council (SRC) but prior to the PIC meeting.*

*Product Development Research:*

*For cycle 23.1, six applications went through due diligence. Following an evaluation of the diligence report, the review panels recommended that the PDRC include the six applications in its final slate of proposed awards The PDRC met on January 23, 2023, and after review and discussion recommended six applications to the PIC for consideration. The applications were submitted in response to the Texas Therapeutics Company Product Development Research Awards RFA, the Texas New Technologies Company Product Development Research Awards RFA, and Seed Awards for Product Development Research RFA.*

*The PDRC's rank order recommends some of the applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities, programmatic review criteria, and the overall program portfolio.*

*The PDRC's recommended slate of six Product Development Research Awards exceeded the available budget for the product development program by more than $25 million. At the February 1, 2023, PIC meeting, Dr. Smith recommended that the PIC defer voting on the recommended slate until a later meeting to allow him time to negotiate the proposed award budgets. To do so, CPRIT CEO Wayne Roberts notified the Oversight Committee on February 6, 2023, that pursuant to T.A.C. § 702.19(e) he granted Dr. Smith a waiver from the general prohibition against communicating with a grant applicant while CPRIT is accepting and reviewing applications. Since February, Dr. Smith*

*and the six proposed applicants have negotiated in good faith to reduce the proposed grant award budgets.*

**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 May 3, 2023, 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 nine applications that were recommended by the Academic Research and Product Development Research Review Councils. Six of these award recommendations had been unanimously deferred by the PIC at their meeting on February 1, 2023. The nine total applications considered by the PIC did not include RR230024 that was recommended by the SRC but withdrawn by the applicant prior to the PIC meeting. The PIC voted to recommend all nine applications to move forward to the Oversight Committee.*

*A review of the CEO affidavits confirms that such affidavits were executed and provided for each grant application recommendation.*