CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS
# RFA 24.2-TDDC

## Texas Diagnostic and Devices Company Awards for Product Development Research

**Please also refer to the Instructions for Applicants document, which CPRIT will post December 1, 2023**

**Preliminary Application Deadline:** December 11, 2023

**Full Application Invitation Issued:** January 24, 2024

**Full Application Deadline:** February 13, 2024

**FY 2024**

Fiscal Year Award Period

September 1, 2023-August 31, 2024

## TABLE OF CONTENTS

## RFA VERSION HISTORY

Rev 11/29/2023 RFA release

# 1. EXECUTIVE SUMMARY

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

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

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

CPRIT has limited funds for company investment in this cycle (approximately $20 million) and has **instituted a maximum award budget cap of $5 million**. Regardless of the amount requested, CPRIT will analyze and negotiate final budgets with grantees in an effort to fund as many worthy projects as possible.

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

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

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

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

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

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

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

## 2. ABOUT CPRIT

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

### 2.1. CPRIT's Statutory Mission

The Texas Legislature has charged CPRIT with the following:

- Create and expedite innovation in cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer.

- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas.

1. 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 2024 are as follows:

- Funding novel projects that offer therapeutic or diagnostic benefits; ie, disruptive technologies
- Funding projects addressing large or challenging unmet medical needs
- Investing in early-stage projects when private capital is least available
- Stimulating commercialization of technologies developed at Texas entities
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff

2. Providing appropriate return on Texas taxpayer investment

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

## 3. FUNDING INFORMATION AND MATCHING FUNDS REQUIREMENT

### 3.1. Overview

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

must fulfill the contractual G&Os associated with 1 funding tranche before receiving the next disbursement of funds.

## 3.2. Funding Stage for Texas Diagnostic and Device Company Awards

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

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

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

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

CPRIT typically does not fund efforts outside of these parameters. Companies that have clinically demonstrated safety and efficacy should be able to acquire necessary capital via other sources; any request for later clinical trials must explicitly justify why CPRIT funding is appropriate. However, by exception, CPRIT may consider later-stage clinical trials and other development activities where exceptional circumstances warrant investment.

## 3.3. Allowable Expenses

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

- Salary and fringe benefits
- Research supplies
- Equipment
- Clinical trial expenses
- Intellectual property (IP) acquisition and protection
- External consultants and service providers
- Travel in support of the project
- Other appropriate research and development costs, subject to certain limitations set forth by Texas law

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

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

## 3.4. Required Matching Funds

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

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

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

# 4. ELIGIBILITY AND RESUBMISSION POLICY

## 4.1. Award Recipients Must Be Texas-based

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

A company headquartered outside of Texas is eligible to apply for a CPRIT award, but the company must fulfill all location requirements identified in the application within 1 year of receiving the initial disbursement of CPRIT funds. Failure to maintain compliance with the location criteria will result in consequences ranging from suspension of grant funding to early termination of the grant contract and repayment of grant funds.

## 4.2. Contributors to CPRIT Ineligible to Receive CPRIT Awards

An applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.

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

An applicant is ineligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.

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

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

## 4.5. Resubmission Policy

A preliminary application previously submitted to CPRIT on or after August 24, 2022, but not recommended for funding, may be resubmitted once and must follow all resubmission guidelines. CPRIT will not count against the resubmission limit an application previously submitted in the FY 2023 or FY2024 review cycle if CPRIT administratively withdrew the preliminary or full application without review.

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

purposes of the resubmission policy if the applicant or CPRIT administratively withdrew the application prior to review.

# 5. APPLICATION REVIEW PROCESS AND CRITERIA

## 5.1. Overview

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

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

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

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

## 5.2. Review Process – Preliminary Applications

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

Preliminary applications must be submitted by December 11, 2023, 4 PM central time. A panel of experts will individually review and score the preliminary application using the criteria listed below. The panel reviewers may meet collectively to discuss the final decision regarding the preliminary application and will decide whether to invite the applicant to submit a full application for award consideration. In January 2024, CPRIT will issue invitations to submit full applications to companies with the best-ranking preliminary application scores. The review process ends after preliminary review for those applicants not invited to submit a full application.

## 5.3. Review Criteria – Preliminary Applications

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

## 5.4. Review Process – Full Applications

### 5.4.1. Product Development and Scientific Review

CPRIT assigns full applications to individual CPRIT product development review panel members for evaluation using the criteria listed in section 5.5. In addition to reviewing the written application, the review panel will provide questions to the company that the company will address during a meeting convened virtually for the applicant to present the application in person. Importantly, the applicant should provide CPRIT with any correspondence that the company has conducted with regulatory agencies (eg, the FDA) in section 8.8.6 of the application and also promptly submit any new correspondence that occurs at any time during the course of the review.

### 5.4.2. Due Diligence Review

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

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

### 5.4.3. Program Integration Committee (PIC) Review

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

### 5.4.4. Oversight Committee Approval

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

## 5.5. Review Criteria – Full Application

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

- Unmet medical need
- Potential clinical impact
- Relevant proof-of-concept studies (including preclinical safety/efficacy studies) and, where relevant, target validity studies supporting expectations of clinical impact
- Proposed Integrated Product Development Plan (IPDP)
- Communications with regulatory agencies

- Present and anticipated competitive landscape, together with justification for assumptions of competitive advantages of product in question
- IP
- Business/commercialization prospects
- Relevant experience and accomplishments of management team and key consultants
- Adequate budget and project timeline paired with realistic G&Os
- Overall commitment to Texas

See the appendix for more information on review criteria.

## 5.6. Confidential, Conflict-Free Review

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

CPRIT will notify an applicant regarding the peer review panel assigned to review the grant application. CPRIT lists the review panel members on our website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

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

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

## 5.8. Prohibited Communication Between Applicant and Reviewers During Review

Except as noted below, CPRIT prohibits communication regarding any aspect of a pending preliminary or full application between the applicant or someone on the grant applicant's behalf and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

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

NOTE: The following individuals are members of the PIC: the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services.

# 6. SUBMISSION GUIDELINES AND DEADLINES

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

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

## 6.1. Online Application Receipt System

Applicants submit preliminary and full applications via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal are eligible for evaluation.** 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 2024 Review Process

The invitation to submit a full application is valid only for the FY 2024 review cycle. An applicant who is invited to submit a full application for the FY 2024 review cycle but does not do so must restart the review process in future fiscal years by resubmitting the preliminary application.

## 6.3. CPRIT Will Honor Invitations to Submit Full Applications for the FY 2024 Review Cycle

Companies that received an invitation to submit a full application in the first cycle of FY 2024 but did not submit the full application before CPRIT closed the review portal on June 30, 2023, may submit a full application for this cycle. However, the maximum award budget limit of $5 million will apply. Companies wishing to submit a full application for this cycle using an invitation issued earlier this fiscal year must notify CPRIT of their intention to do so by January 16. 2024.

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

Preliminary Applications: An applicant may submit a preliminary application via CARS by December 11, 2023, 4 PM central time. Following the review and scoring of all preliminary applications, CPRIT will issue a limited number of invitations to submit a full application in January 2024 to the companies with the best ranking scores.

Full Applications: CPRIT will convene panels for review of full applications submitted by the February 13, 2024, deadline. Key dates for the second FY 2024 review cycle are as follows:

**FY 2024 Review Cycle 2**

| | |
|---|---|
| Full Application Deadline | February 13, 2024; 4 PM central time |
| In-Person Presentation | Mid-March 2024 |
| Due Diligence | March-April 2024 |
| Oversight Committee Meeting | May 15, 2024 |

## 6.5. Submission Deadline Extensions

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

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

CPRIT urges applicants to initiate the registration process in CARS 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. Abstract (maximum 1,500 characters)

Explain the question or problem to be addressed and the approach to its answer or solution. The aims of the application should be obvious from the abstract although they need not be restated verbatim from the research plan. Address how the proposed project, if successful, will have an impact on cancer. Describe the unmet medical need addressed by the proposed project. Briefly explain the product, service, technology, or infrastructure proposed and funding needs.

## 7.2. Executive Summary (maximum 2 pages)

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

a. Brief description of the device or diagnostic test
b. Unmet medical need, including clear description of the expected clinical use criteria and resulting impact on clinical pathway
c. Proof of concept, including clear description of rationale for design of studies, as well as choice of any algorithms/software (eg, AI/ML) used to process data
d. Product validation, including clear rationale for statistical interpretation of any algorithms/software (eg, AI/ML) used to process data from studies, leading to resulting projected clinical performance expectations
e. Safety characterization to date
f. Manufacturing development status
g. Regulatory status and plan (eg, brief summary of agency interactions to date, **including any communications with a regulatory agency, US or foreign,** and planned, likely regulatory paths)
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

## 7.3. Slide Presentation (maximum 16 slides)

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

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

Succinctly describe the aims of the proposed project. Provide an anticipated budget request for the project, linking the aims to expected budget amounts. Should CPRIT invite the applicant to

submit a full application, the proposed aims and budget will serve as the basis for the project G&Os and requested budget.

### 7.5. Resubmission Summary (maximum 1 page)

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

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

## 8. FULL APPLICATION COMPONENTS

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

### 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:

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

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

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

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

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

## 8.4. Executive Summary (maximum 2 pages)

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

a. Brief description of the device or diagnostic test
b. Unmet medical need, including clear description of the expected clinical use criteria and resulting impact on clinical pathway
c. Proof of concept, including clear description of rationale for design of studies, as well as choice of any algorithms/software (eg, AI/ML) used to process data
d. Product validation, including clear rationale for statistical interpretation of any algorithms/software (eg, AI/ML) used to process data from studies, leading to resulting projected clinical performance expectations
e. Safety characterization to date
f. Manufacturing development status
g. Regulatory status and plan (eg, brief summary of agency interactions to date, **including any communications with a regulatory agency, US or foreign,** and planned, likely regulatory paths)

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 2 pages)

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

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

## 8.8. Integrated Product Development Plan (IPDP) (maximum 12 pages)

### 8.8.1. Overview

An IPDP consists of the following:

a. The work already done that substantiates the rationale and lays the foundation for the work proposed in the application
b. The detailed development plan and proposed work over the duration of the application
c. The design, production, manufacturing, and controls plan
d. The regulatory activities and timelines associated with each plan
e. Copies of all communications with any regulatory agency, US or foreign

The IPDP should be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, data should drive the IPDP.

A comprehensive IPDP includes information for clinical, nonclinical, and manufacturing studies through marketing application along with any regulatory strategies. It should allow the applicant to construct a detailed timeline (eg, Gantt chart) incorporating the different disciplinary studies into 1 cohesive document to allow for assessment of risks if studies are incomplete by the original timeline. Reviewers will assess the accuracy of proposed timelines for conduct of clinical studies evaluating anticipated rates of recruitment considering any competing clinical studies, completion of nonclinical studies prior to regulatory submissions, and adequacy of any required assay development supporting the development of the medical diagnostic or medical device.

The IPDP also demonstrates the applicant's thorough grasp of the risks associated with their development program. Inclusion of go/no-go decision points assists the reviewers when evaluating the commercial astuteness of the applicant. The applicant should supplement this information with appropriate market entry strategy considering both the current competitive landscape as well as competitive products in development.

Applicants may provide references for the IPDP section as a standalone document that the applicant will separately upload into CARS. In the interest of brevity, include only the most pertinent and current literature. While references will not count toward the IPDP section page limit, it is essential to be concise and to select only those references relevant to the IPDP. Do not use the references to circumvent IPDP section page limits by including data analysis or other nonbibliographic material.

This section highlights components of the IPDP that are of fundamental importance during the peer review and scoring process. Please note that this may not be all inclusive. When addressing future work, use the appropriate sections below as guidance. CPRIT recognizes that applications addressing early-stage research may not have information for all sections.

### 8.8.2. Target Product Profile (TPP)

A target product profile (TPP) that projects a clear path to full commercialization is essential to a solid IPDP. The TPP serves as a summary of the product development program described in terms of a marketed label with supporting data. It includes information on conducted and planned studies and serves to facilitate the company's interactions with regulatory authorities. The comprehensive TPP may also include commercial information, IP positions, and ultimately go/no-go decision criteria to determine whether a product development program should proceed or end. NOTE: While the TPP for a PMA will be more elaborate than one for 510(k), CPRIT requires a TPP for all products proposed for development in the application.

Because the TPP is an abstract of the IPDP, CPRIT encourages the applicant to complete the TPP prior to drafting the IPDP. The applicant may employ a basic or comprehensive approach to the TPP. Many companies follow the format based on the Medical Device and In Vitro Diagnostic labeling guidance (https://www.fda.gov/media/74034/download) to create the TPP.

CPRIT considers the following topics appropriate for a comprehensive TPP:

Diagnostic Commercialization

a. Type of diagnostic product: molecular/cellular/imaging markers (referred to as "markers" or "biomarkers") and assays for cancer detection, diagnosis, prognosis, monitoring, and prediction of response or resistance to treatment; markers for cancer prevention and control; companion diagnostic to a therapy; development of diagnostic tests to distinguish high-risk early lesions from less risky cancers; development and/or clinical validation of

analytical assays to be used in cancer treatment, control, or prevention trials; validation of pharmacodynamic markers and markers of toxicity.

Applicants should have assays that work on human samples and whose importance is well justified for development into clinical assays. As clinicians often combine chemotherapies and/or radiation therapies with immunotherapies to enhance durability of anticancer responses, assays for measuring multiple markers, including immune markers, can be developed and validated simultaneously.

Device Commercialization

a. Type of device, including pictorial representations each of the functional components or elements of the device if the device consists of more than 1 physical component or element; The principles of operation of the device
b. The methods, facilities, and controls used in the manufacture, processing, packing, storage, and where appropriate, installation of the device in sufficient detail so that a person generally familiar with current good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.
c. Intended uses: treatment, therapeutic treatment decision, detection, diagnosis, prognosis, prediction, monitoring
d. Unmet need
e. Stage of development of the product: proof-of-concept, prototype, validation, clinical
f. Product validation: Describe nonclinical and clinical trial data and designs intended to demonstrate device use and/or diagnostic effects.
g. Manufacturing of prototype, scaleup, commercial scale
    1) Type and methods for quality measurement planned in QA/QC
    2) Assessment of quality versus cost (cost of goods [COGs] below) at expected commercial scale
h. Regulatory pathway: 510(k), PMA
i. Completed and planned studies for marketing approval, if applicable
    1) Performance testing to establish substantial equivalence with a predicate device
    2) Proposed labeling
    3) Safety characterization to date
    4) Manufacturing development status

5) Clinical trial status and plans forward covered by the grant
6) Biocompatibility of any patient contacting materials
7) EMC and electrical safety of medical devices incorporating electronic components
8) Software documentation for devices containing or utilizing software
9) Verification and validation of sterilization and shelf life
10) Summary of nonclinical laboratory studies
11) Summary of the clinical investigations including a discussion of subject selection and exclusion criteria, study population demographics, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, device failures and replacements

j. IP
k. Licensing agreements
l. Competitive analysis
m. Commercialization pathway and strategy
   1) Target COGs
   2) Reimbursement strategy

### 8.8.3. Product Validation

a. Describe the independent validation of the product through external work by associates or competitors. If the product detects or measures biomarkers, demonstrate or cite to what extent the biomarkers have been validated, eg, through knockdown studies and/or measuring expression in disease models or patients' samples.
b. Describe the robustness of the development process to include accuracy; specificity and precision of any nonclinical, clinical, and analytical assays; and the uniqueness of the target in cancer cells.
c. Document the compliance of your process and materials regarding International Organization for Standardization standards and good manufacturing processes. Provide a clear summary describing the stage of product development (fully validated, prototyped, tested in clinical setting) with emphasis on demonstration of proof of principle, and if clinical studies are required, adequate data summaries for conducted studies or detailed design elements for future studies.

### 8.8.4. Clinical Study Development Plan

If the company proposes to carry out clinical studies with CPRIT funds, such studies must include scientifically valid designs, regulatory validated clinical end points, appropriate patient population and sample size, adequate duration of exposure and follow-up, and regulatory acceptable controls.

NOTE: As set forth in section 8.8.6, the applicant must provide any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application.

Describe the study design, including the following information:

a. Patient population, including the case and control groups (if applicable). The applicant should document the inclusion and exclusion criteria for the trial, explain the appropriateness of patient populations from a safety perspective, and justify the generalizability of results to TPP patient population.
b. Randomization scheme and/or comparator/control arm. In the case of controls, justify the choice of control.
c. Justification for clinical trial sample size including statistical considerations.
d. Justification of target efficacy effect size if applicable, eg, if the company intends the study to support accelerated approval, general approval, or inform go/no-go decision-making.
e. Discuss clinical relevance of target effect size.
f. Adaptive study designs (Bayesian or frequentist) should be clear on design criteria and clinical rationale. For sequential designs with interim analyses, define the impact on design criteria and power. Also define relevant stopping rules and related justification of expected clinical performance criteria.
g. Study implementation information describing the number of investigational sites and the estimated patients enrolled per site. Explain whether the site has competing study protocols and how this will impact accrual. Describe the incidence/numbers of patients meeting patient population description per site. Discuss initiatives the company plans to address recruitment challenges. Detail the study activities that the company will contract out versus activities it will manage internally. Demonstrate that relevant clinical

operations experience is present within the study team.

h. Study timeline, including key startup activities (see below).
i. Study budget broken down by major cost/driver areas, and a fully inclusive figure representing the total study budget.
j. Describe the extent of contract research organization (CRO) input into budget preparation and include any quotations/estimates from any CROs or other third parties providing clinical trial services in the Budget Justification (see section 8.12).

### 8.8.5. Regulatory Plan

Regulatory input on the company's TPP is critical to finalize the clinical, nonclinical, and manufacturing studies that define the IPDP. While companies may plan an exit strategy prior to bringing a product to late-stage development or to the market, the development and adherence to a logical, expeditious, and fully integrated regulatory plan are advisable to maximize value for any potential purchaser.

Accordingly, the Regulatory Plan is an important part of the CPRIT application and an opportunity for the successful applicant to demonstrate proficiency and expertise. In detailing the proposed regulatory plan the applicant should address the following considerations and topics:

a. Identify the point of contact with regulatory authorities. The individual communicating with the FDA should have experience and a successful track record interacting with regulatory authorities, preferably having brought products to the market.
b. The timing of development meetings with regulatory authorities.

### 8.8.6. Regulatory Correspondence Documentation

Applicants must upload as a standalone document copies of any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (eg, FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application. This is a continuing obligation that extends over the course of the review process. If the applicant receives meeting minutes after submitting the application but before CPRIT has made a final decision on the application, the applicant should contact the CPRIT Helpdesk (see section 10.1) for assistance on filing the additional information.

### 8.8.7. Design/Production/Manufacturing

The applicant must have sufficient expertise and resources to address necessary design, production, and manufacturing activities, including scaling up in preparation of the documentation required for the IDE submission and, eventually, the 510(k) or PMA. The applicant should consider enlisting the services of an individual who has been responsible for the successful development of several products that have attained marketing approval.

The individual(s) responsible for the manufacture of the medical device or diagnostic must ensure that the proposed G&Os are in line with the state of the development of the product. The timelines for the development of the product must be reasonable and realistic with appropriate assessments of risks and risk management plans to address potential risks. Applicants should explain the commercialization of the product and a comprehensive description of the anticipated COGs, including the program management of anticipated contractors and the sourcing of raw materials, reagents, supplies, and instruments.

## 8.9. Business Plan

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

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

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

### 8.9.1. Business Rationale (maximum 2 pages)

Provide the business rationale for investing in this project. Successful applicants will provide a thoughtful, careful, and succinct business justification explaining why this project is an appropriate investment of CPRIT and private funds.

### 8.9.2. Product and Market (maximum 1 page)

While the applicant will also provide information on the product and potential market when creating the IPDP required pursuant to section 8.8, including an overview of the product and method of delivery, describing the unmet medical need, and explaining the potential market in this section provide context for rest of the business plan.

a. Explain the unmet medical need with particular focus on patient populations contemplated for initial target indication(s): incidence/prevalence, life expectancy/survival, morbidity, annual mortality figures. Assuming the successful achievement of development objectives, describe how the intended product significantly addresses an unmet medical need in the diagnosis and/or treatment (including supportive care) and prognosis, or prevention of cancer.
b. Describe the initial target market and how the product fits within the standard of care (SOC), ie, how the innovative product will impact the clinical care pathway, both in terms of the criteria of use/adoption as well as the downstream clinical impact. This will range from innovations that will displace existing diagnostics/devices through superior performance in current SOC pathways, to diagnostic/device innovations that create novel, improved clinical pathways with different decision processes for improved patient outcomes. Patient populations should be broadly comparable to those included in the pivotal trials. Define patient population sizes by market segments.

### 8.9.3. Competition and Value Proposition (maximum 1 page)

a. Provide an overview of the competitive environment (current and anticipated) and how the envisioned product will compete in the marketplace.
b. Analyze the strengths and weaknesses of the proposed product compared to current and potential future products, including any significant improvements over the current SOC such as a better safety profile, reduced costs, improved compliance, and improved convenience. A clear delineation of competitive advantages, including supporting

summary data, is important.

### 8.9.4. Clinical and Regulatory Plans (maximum 1 page)

Provide an overview of the regulatory strategy, including preclinical and clinical activities and the regulatory pathway for major markets.

a. Include summary descriptions of regulatory communications (including all interactions to date with the FDA) and a description of how the company incorporated feedback from regulatory authorities.
b. If the application includes clinical research, present a plan to achieve realistic accrual rates of patients that meet the inclusion/exclusion criteria within the proposed timeline.

### 8.9.5. Pricing and Reimbursement (maximum 1 page)

Provide an overview of the projected product cost and anticipated revenue. Cost, price, and reimbursement references from similar products are helpful. An overview of how the company plans to obtain CMS and private insurance reimbursement approval is also helpful. An excellent application will include financial modeling on expected clinical pathway cost changes over populations indicated for an innovative diagnostic or device application, and such cost changes will be analyzed with respect to clinical benefit to anticipate insurance/reimbursement decisions. In particular, depending on clinical application, reimbursement for diagnostics can be highly sensitive to false-positive and false-negative statistical performance rates, and these should be addressed as applicable.

### 8.9.6. Commercial Strategy (maximum 1 page)

Provide an overview of the company's financial projections and how the company plans to generate a return on this investment.

a. Describe how the company plans to bring the product to market. Information on targeted physicians, sales channels, etc, is helpful.
b. Alternatively, if the company's plan includes acquisition by a larger medical device/pharmaceutical/HIT company, etc, provide an overview of similar transactions.

### 8.9.7. Risk Analysis (maximum 1 page)

Describe the specific risks inherent to the product plan and how the company plans to mitigate those risks. Key risk issues typically include efficacy versus competitors, clinical trial

implementation and conduct, FDA approval, production and manufacturing, changing competitive environment, etc.

### 8.9.8. Funding to Date (this section may exceed 1 page, if necessary)

Provide an overview of the funding received by the company, including a list of funding sources and a comprehensive capitalization table that comprises all parties with investments, stock, or rights in the company. CPRIT provides a template for a capitalization table in the application materials that the applicant **must** use when completing the application. The applicant must list identities of all parties and may exceed the 1-page limit if necessary to fully capture all funding sources. It is not appropriate to list any funding source as anonymous.

### 8.9.9. Company Financial Overview (maximum 1 page)

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

### 8.9.10. Intellectual Property (IP)/Freedom to Operate (maximum 1 page)

a. List patents/patent applications together with jurisdictions, ownership/licensing aspects, status, and filing and expiration dates.
b. Indicate by patent/patent application the nature of key claims, viz, COM, methods, uses, sample/tissue/cell prep process IP, material science IP for devices, etc, and what specifically would such claims prevent a competitor from doing. In this respect, include a discussion of the ease of workaround by a potential competitor. For any algorithm and/or software components key to differentiated competitive performance of a diagnostic or device, please clearly discuss trade-off and decisions regarding trade secret, copyright, and IP to protect against competitive threats.
c. For future/anticipated patent filings, indicate whether such filings will be continuation in part as opposed to divisional or novel/standalone patents.
d. Discuss potential for exclusivity as well as the potential contribution of trade secrets to protection from competition.
e. Describe freedom to operate, licensing status/plans.

### 8.9.11. Management Team and Key Personnel (maximum 1 page)

The applicant's management team should be composed of individuals who have the appropriate level of experience in developing and commercializing products. The team should include appropriate disciplinary experts in product engineering, clinical development, nonclinical development, product design, manufacturing, regulatory strategy, commercialization and fundraising. An experienced program manager who has coordinated product development activities to product approval is desired. Team members, either consultants or company employees, must have sufficient time to devote to development activities allocated in the application.

For each member of the senior management and scientific team, provide a paragraph summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Also indicate the percentage of the person's time devoted to the project. The time indicated by the company is an obligatory commitment, regardless of whether they request salaries or compensation. "Zero percent" effort or "TBD" or "as needed" are not acceptable levels of involvement for those designated as key personnel.

Provide the same information for other key personnel who contribute to the development or the execution of the project in a substantive, measurable way. ("Substantive" means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. "Measurable" means that they devote a specified percentage of time to the project.) NOTE: While the applicant should identify all participants who meet these criteria as "key personnel," CPRIT expects that the applicant will keep to a minimum the number individuals designated as key personnel.

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

Provide a biographical sketch for up to 4 key scientific personnel describing their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. CPRIT provides an optional "Product Development Research Programs: Biographical Sketch" template for the applicant's use. The NIH biographical sketch format is also appropriate.

## 8.11. Commitment to Texas (maximum 1 page)

Describe the company's commitment to locating in Texas and maintaining its business presence in the state. Please identify the criteria specified in section 4.1 "Award Recipients Must Be Texas-Based" 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

Due to the limited amount of remaining FY 2024 award funds available for Product Development Research Program awards, CPRIT is capping the total amount of award funds that may be requested by the applicant at $5 million.

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

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

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

a. Identify the specific equipment that the company proposes to purchase with grant funds. Items that the company includes in the "equipment" budget line should have a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit.
b. Texas Health and Safety Code Section 102.203(d) limits the amount of grant funds that companies may spend on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). CPRIT's Administrative Rules provide guidance regarding indirect cost recovery.

c. The total amount of CPRIT funds allowed for an individual's FY 2024 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 2024 salary cap and future salary caps at its discretion.

The Budget section is composed of 4 subtabs:

a. **Budget for All Project Personnel:** Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project. If the company requests funding for a role that the company has not yet filled at the time of submission, the applicant should note "new hire" as name.
b. **Detailed Budget for Year 1:** Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Contractual (Subaward/Services Contracts), or Other. This section should include only the amount requested from CPRIT. DO NOT include the amount of the matching funds or the budget for the entire proposed period of performance.
c. **Budget for Entire Proposed Period of Performance:** Provide the amount requested from CPRIT for direct costs for all subsequent years. CARS will automatically populate the amounts for *Budget Year 1* based on the information provided in the previous subtabs. This section should include only the amount requested from CPRIT. DO NOT include the amount of the matching funds.
d. **Budget Justification:** The budget should align with the proposed G&Os. Provide a compelling justification for the budget for each line item of the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. For projects that involve CROs or other third parties providing clinical trial services, include quotations/estimates from the CRO/other third parties. If travel costs will include out-of-state or international travel, make that clear here. This section should include CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds.

# 9. AWARD CONTRACTS

## 9.1. Overview

Texas law requires that CPRIT award grant funds via a contract between the company and CPRIT. Contract negotiation commences after the CPRIT Oversight Committee votes to approve an application for a grant award. Texas law specifies several contract terms that CPRIT must include in the executed agreement, including terms relating to revenue sharing and IP rights, matching funds, and required reporting for fiscal, progress, and compliance.

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

## 9.2. Revenue-Sharing Terms

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

## 9.3. Matching Funds

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

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

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

- For companies receiving $20 million or less from CPRIT (inclusive of previous CPRIT awards), the company must dedicate to the project at least $1 of funds under the company's control for every $2 of CPRIT grant award funds.
- A company approved for 1 or more CPRIT product development grants that together total a commitment of more than $20 million must increase their matching fund obligation to at least $1 for every $1 contributed by CPRIT.

  The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under CPRIT's matching funds policy, the company must dedicate at least $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.
- A company approved for 1 or more CPRIT product development grants that together total a commitment of more than $30 million must contribute at least $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

# 10. CONTACT INFORMATION

## 10.1. Helpdesk

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration and online submission of applications. Helpdesk staff cannot answer questions regarding scientific and product development aspects of applications. Before contacting the Helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. For "Frequently Asked Technical Questions," please go here.

| | |
|---|---|
| Hours of operation: | Monday through Friday, 8:00 AM to 6:00 PM central time |
| Tel: | 866-941-7146 (toll free in the United States only - international applicants should use the email address below) |
| Email: | Help@CPRITGrants.org |

## 10.2. Programmatic Questions

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

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

# 11. APPENDIX - REVIEWER EVALUATION GUIDELINES

## 11.1. Primary Review Criteria (Scored)

### 11.1.1. Unmet Medical Need

a. Assuming successful accomplishment of development objectives, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
b. In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

### 11.1.2. Product Validation

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

### 11.1.3. Production/Manufacturing

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

### 11.1.4 Intellectual Property (IP)/Freedom to Operate

a. Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique know-how?
b. Does the company have issued patents? If not, have they conducted freedom-to-operate and patentability analysis?
c. Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?

d. Are there opportunities for meaningful patent life extension?
e. Has the applicant secured appropriate licenses conferring freedom to operate, if required?

### 11.1.5 Market Opportunity

a. Does the product address a clearly defined unmet need, eg, lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?
b. Are target indication and market clearly defined?
c. Is a channel to market available? Does the company understand the entire value chain and all constituencies involved in procuring and utilizing the product?
d. Does the company understand the clinical pathway that leads to utilizing the product?
e. Is market opportunity of significant size and lucrative enough to justify investment?
f. Has the applicant demonstrated time or cost savings?
g. How does product fit with existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

### 11.1.6 Competition

a. Is this a "whole product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
b. Is value proposition clearly delineated, ie, improve efficacy, improve safety, reduce cost, or improve convenience?
c. Has the company demonstrated its value proposition versus competition?
d. Has the company conducted a competitive analysis? Does it provide a comprehensive, realistic assessment of strengths and weakness versus competition based on the data generated to date?

### 11.1.7 Development Plan/Regulatory Aspects

a. Have a comprehensive development plan and market entry strategy been developed? How realistic are these plans?
b. Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

### 11.1.8 Management Team

a. Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
b. Does the company have experienced and appropriately accomplished in-house personnel in such key areas as product engineering, clinical development, regulatory affairs, manufacturing, etc? If not, are there plans to address such deficiencies?
c. Has the applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

### 11.1.9 Business/Commercial Aspects

a. Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
b. Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?
c. Has the company clearly anticipated pricing strategy and reimbursement environment?
d. Is the projected return on investment congruent with investment opportunity and risks?

### 11.1.10 Funding

a. Is investor interest in this sector sufficient to fund the company through profitability?
b. Does the applicant already have available funds to meet the CPRIT matching requirement, or do they need to raise additional funds? In this case, how realistic are assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
c. Have likely acquirers been identified by the applicant?
d. Does the company have the resources to support required activities while fundraising?
e. Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program reasonably support such expectations?

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

a. Are the budget and duration of support appropriate for the program of studies described in the application?
b. Is there sufficient clarity in the budget proposal as to how funds will be expended?
c. Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
d. Do plans reflect a substantial commitment to Texas? Does the applicant demonstrate an understanding of the Texas spending requirement for CPRIT funds?