CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA C-16-2-TXCO

Texas Company Product Development Awards

Please also refer to the Instructions for Applicants document, which will be posted January 14, 2016

Application Receipt Opening Date: January 14, 2016

Application Receipt Closing Date: February 25, 2016

FY 2016

Fiscal Year Award Period

September 1, 2015–August 31, 2016

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RFA VERSION HISTORY

Rev 12/28/15 RFA release

1. KEY POINTS

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

- Company applicants must be based in Texas at the time the application is submitted.
- Recipient companies must currently have or must commit to having their headquarters and substantially all staff residing in or relocated to Texas (see section 8.1). The Cancer Prevention and Research Institute of Texas (CPRIT) requires the use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities.
- Of the total project budget, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be designated for the CPRIT-funded project but may be spent outside of Texas.
- CPRIT's contribution to the project will not be greater than $20 million.
- Funding will be tranched and tied to the achievement of contract-specified milestones.
- Funding award contracts will include a revenue-sharing agreement according to CPRIT's policies in force at the time of the award. A copy of the revenue-sharing agreement can be found at www.cprit.state.tx.us. The agreement will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are also available at www.cprit.state.tx.us.
- Renewal applications will be accepted (see section 8.3 and section 10.4.8).
- An application last submitted (including resubmission) before February 1, 2014, may be submitted as a new application, even if it was previously resubmitted (see section 8.2).

2. ABOUT CPRIT

The state of Texas established CPRIT, which may issue up to $3 billion in general obligation bonds to fund grants for cancer research and prevention.

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

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Program Priorities

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

Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of patients with cancer
- Creation of good, high-paying jobs for Texans

- Sound financial return on the monies invested
- Development of the Texas high-tech life sciences business environment

Product Development Program Priorities
• Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market • Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace • Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention

3. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This RFA solicits applications for the research and development of innovative products addressing critically important needs related to diagnosis, prevention, and/or treatment of cancer and the product development infrastructure needed to support these efforts. CPRIT encourages applicants who seek to apply or develop state-of-the-art products, services (eg, contract research organization services), technologies, tools, and/or resources for cancer research, prevention, or treatment. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure.

4. MECHANISM OF SUPPORT

The goal of the Texas Company Product Development Award is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will provide companies or limited partnerships located and headquartered in Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish

infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

5. OBJECTIVES

The long-term objective of this award is to support commercially oriented therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA (with the exception of infrastructure applications) should be the intent to further the research and development of products that would eventually be approved for marketing for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of research and development include translational research, proof-of-concept studies, preclinical studies, and phase 1 or phase 2 clinical trials. By exception, phase 3 clinical trials and later-stage product development projects will be considered where circumstances warrant CPRIT investment.

CPRIT's objectives and program priorities are established by its Oversight Committee. Consistent with the above, these priorities include, "funding projects at Texas companies and relocating companies that are most likely to bring important products to the market." A full description of CPRIT's program priorities may be found at http://www.cprit.state.tx.us/about-cprit/reports/.

6. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development project proposed. Requested funds must be well justified. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property protection, external consultants and service providers, and other appropriate research and development costs, subject to certain limitations set forth by Texas state

law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state of Texas. Texas state law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

Consistent with statutory mandate, of the total project budget, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be made on a year-by-year basis.

7. KEY DATES

RFA release	December 28, 2015
Online application opens	January 14, 2016, 7 AM central time
Applications due	February 25, 2016, 3 PM central time
Invitations to present sent	April 2016
Notifications sent if not invited	April 2016
Presentations to CPRIT*	May 2016
Award Notification	August 2016
Anticipated Start Date	August 2016

* Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

8. ELIGIBILITY

8.1. New Applications

- Recipient companies must be Texas based and currently have or must commit to the following: Company headquarters in Texas; all C-level executives residing in Texas (exceptions must be well justified and approved by CPRIT); key business functions (R&D, operations, clinical, regulatory, sales, marketing business management) and substantially all personnel, along with appropriate management, relocated to or hired from within Texas. This requirement does not apply to field-based clinical and sales staff. The company will remain in Texas for a specified period after funding and use Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities. To the extent that Texas-based subcontractors or collaborators are not available or cost effective, non-Texas-based collaborators and subcontractors may be used, but reimbursement of associated costs may not be available.
- An application last submitted (including resubmissions) before February 1, 2014, may be submitted as a new application, even if it was previously resubmitted.
- Only 1 coapplicant may be included on the application. For the Product Development Program, a coapplicant is an individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, coapplicants share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple applicants are named, each is responsible and accountable for the proper conduct of the project, program, or activity including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.
- A company applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individual within the second degree of consanguinity or

affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.

- A company applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The company applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or other individuals are ineligible to receive federal grant funds or have had a grant terminated for cause, the applicant may be contacted to provide more information.
- CPRIT grants will be awarded by contract to successful company applicants. Certain contractual requirements are mandated by Texas state law or by administrative rules. Although the company applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

8.2. Resubmission Policy

- An application previously submitted to CPRIT within the last 2 years (after February 1, 2014) but not funded may be resubmitted once and must follow all resubmission guidelines (see section 10.4.7). **An application that was last submitted (including a resubmission to CPRIT) before February 1, 2014 may be submitted as a new application, even if the most recent submittal prior to February 1, 2014, was a resubmission.** It is expected that significant progress will have been made on the project; a simple revision of the prior application with editorial or technical changes is not

sufficient, and applicants are advised not to submit an application with such modest changes.

- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. An application that was administratively withdrawn by the applicant or by CPRIT prior to review by the review panel is not considered a submission for purposes of CPRIT's resubmission policy.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

8.3. Renewal Policy

- A grant recipient that has previously been awarded grant funding from CPRIT may submit an application under this mechanism to be considered for a competitive renewal. The eligibility criteria described in section 8 also apply to renewal applications. In addition, note the following:
- Applicants must have received a CPRIT award—a Company Commercialization Award (this mechanism was called Company Investment in FY 2010), a Company Formation Award, a Company Relocation Award, a New Company Award, or an Established Company Award.

- Before submitting a renewal application, applicants must consult with the Product Development Programmatic Office (see section 13.2) to determine whether it is appropriate for their company to seek renewal funding at this time.

9. APPLICATION REVIEW

9.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT requires the submission of a comprehensive scientific plan (see section 10.4.9) and a detailed business plan (see section 10.4.10). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and scientific plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made by the review process described below.

9.2. Review Process

- **Product Development and Scientific Review:** Applications that pass initial administrative compliance review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of company applicants may be invited to deliver in-person presentations to the review panel.
- **Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—intellectual property, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications will be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due

diligence and intellectual property reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.

- **Program Integration Committee Review:** Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.
- **Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.2.1. Confidentiality of Review

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

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.

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

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

9.3. Review Criteria

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

9.3.1. Primary Criteria

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

Primary criteria include the following:

Significance and Impact: Will the outcomes of this CPRIT-funded project result in the development of innovative products with significant product development potential? Will the outcome substantially impact the diagnosis, treatment, or prevention of cancer, or supportive care for patients with cancer? How would competing products or services affect the value of the proposed offering?

Product: Is there demonstrated proof of relevance, and does the product fulfill a clear, unmet medical or infrastructure need? Has work been conducted that supports the advancement of the proposed product, service, or technology? Can the product be produced or manufactured in a commercially viable fashion?

Market Plan: Is there a realistic assessment of the unmet clinical need, market size, and expected penetration? Has management adequately assessed potential competitors and described how the company's offering will successfully compete with them? Has the applicant addressed patients, market segments, value proposition, pricing, outcomes research, sales plans, marketing research plans, or results? If the applicants plans to seek acquisition by a strategic partner, is there a well-characterized analysis of exit strategy and valuation? Is there an appropriate basis for a reimbursement strategy?

Development Plan and/or Clinical and Regulatory Path: Is the development plan and/or clinical and regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both a positive and a negative outcome? Does the budget appropriately support the plan? Is there clarity on regulatory matters and current regulatory strategies?

Competitive Landscape/Intellectual Property: Is the applicant aware of the competitive landscape related to his/her project? Has the applicant demonstrated an understanding of the products and treatment under development that will be in competition with the company's product at the time of product introduction? Have intellectual property issues been addressed?

Scientific Plan: Is the proposed product, service, and/or infrastructure based on a feasible research framework, hypothesis, and/or goal? Are the methods appropriate, and are potential research and developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the applicant have the appropriate level of management experience to execute the stated strategy? Does the team have the needed experience or access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan? Does the management team have experience in obtaining results that are directly relevant to the proposed project (eg, product development and registration)?

Financial Plan: Is there a comprehensive analysis of the aggregate funding required to market or exit and strategy to raise the required funding? Has the applicant demonstrated that the returns are sufficient to justify the investment on a risk-adjusted basis?

9.3.2. Secondary Criteria

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

Secondary criteria include the following:

Budget and Duration of Support: Are the budget and duration appropriate for the proposed project? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is it clear how funds will be used? Does the proposed investment fund the research and development of the proposed product, service, or technology to a point where, if the results are positive, it is likely that the project will be able to attract further financial support outside of CPRIT?

10. SUBMISSION GUIDELINES

Applicants are advised to carefully review all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Applications that are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

10.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The company applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (an individual authorized to sign and submit an application

on behalf of the company applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. It is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires the applicant and the ASO have 2 different accounts and user names. Applications will be accepted beginning at 7 AM central time on January 14, 2016, and must be submitted by 3 PM central time on February 25, 2016. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.2. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. Late submissions are permitted only in exceptional instances, usually for technology failures. Applicants should allow sufficient time to familiarize themselves with the application format and instructions to avoid unexpected issues. The applicant's failure to adequately plan is not sufficient grounds to justify approval of a late submission.

Peer review schedules are set far in advance and do not accommodate receipt of an application days after the deadline. Therefore, potential applicants that are unable to meet the deadline due to issues such as travel, sabbaticals, conferences, prolonged illness, or other leave, etc, should not request additional time to submit an application but should instead consider submitting the application in the next review cycle.

A request to extend the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

10.3. Product Development Review Fee

All applicants must submit a fee of $1,000 for product development review. Payment should be made by check or money order payable to CPRIT; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit the application fee after the deadline has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed to the following address:

Cancer Prevention and Research Institute of Texas
P.O. Box 12097
Austin, TX 78711

10.4. Application Components

Applicants are advised to minimize repetition between application components to the extent possible. In addition, applicants should use discretion in cross-referencing sections in order to maximize the amount of information presented within the page limits.

10.4.1. Executive Summary (1-page maximum)

Provide an executive summary that clearly explains the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.4.2. Slide Presentation (10-page maximum)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with 1 slide filling each landscape-orientated page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.4.3. Abstract and Significance (5,000-character maximum)

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

if successful, will have a major impact on care of patients with cancer. Explain how this application provides a clear path for acquiring proof-of-principle data necessary for next-stage commercial development.

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

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The Layperson's Summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

10.4.5. Goals and Objectives (maximum of 1,200 characters each)

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

10.4.6. Timeline (1-page maximum)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

10.4.7. Resubmission Summary (1-page maximum)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application submitted or resubmitted before February 1, 2014, may be submitted as a new application, even if it was previously resubmitted. For the "new" applications, no summary is required.

10.4.8. Renewal Justification Summary (1-page maximum)

If this is a renewal, upload a summary that briefly outlines the progress made with the initial CPRIT award and outlines the proposed use of renewal funding and the resulting value for Texas. Clearly indicate whether (1) the technological/scientific underpinning is the same as that evaluated during review of the company's originally funded CPRIT application or (2) whether funding is sought for the research and development of a new product or service not previously reviewed by CPRIT or represents a significant modification of the original product or service reviewed by CPRIT (either option is acceptable). If this is not a renewal, no summary is required.

10.4.9. Scientific Plan (15-page maximum)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims. Outline the steps to be taken during the proposed period of the award, including the design of the translational or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The Scientific Plan should include a defined Target Product Profile that projects a clear path to full commercial development. The Target Product Profile should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, diagnostic, or medical device that could be useful in the treatment of cancer?
- Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
- Description of a high-level clinical development plan detailing each of the clinical studies 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.

Additionally, for therapeutics, the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or will the use of this new agent require a paradigm shift (more frequent or less frequent dosing, new route of administration), and if so, what impact will it have on current standard of care?

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

- Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced;
- Absorption, distribution, metabolism, excretion, including, but not limited to, relevant studies based on route of administration;
- Safety (studies as mandated by ICH Guidelines);

- Biomarkers (assays) that potentially target specific patient populations for clinical trials;
- Biomarkers (assays) that can serve as potential pharmacodynamic markers of clinical activity during early clinical trials designed to demonstrate proof of concept;
- Proposed current good manufacturing practice (including estimated costs) that can be scalable from phase 1 through phase 3. Include information if there are possible plans for formulation.

The scientific plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by the highly qualified group of reviewers. To the extent possible, the scientific 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.

10.4.10. Business Plan (15-page maximum)

Provide a business plan covering all of the topics below in the order shown. Successful applicants will make thoughtful, careful, and economical use of the limited space. Note that if the company is selected to undergo due diligence, information to support a full intellectual property review will be requested at that time. Applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

A. **Product and Market:** Provide a brief description of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care. To the fullest degree possible, describe patients, market segments, value proposition, pricing, outcomes research, sales plans, marketing research plans, or results.

B. **Clinical and Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities and the regulatory pathway for major markets. Please describe how this is driven by interactions with the Food and Drug Administration (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.

C. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated.

D. **Current and Pending Support:** Provide an overview of the funding received, including a list of funding sources and a comprehensive cap table that should comprise all parties who have investments, stock, or rights in the company. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.

E. **Financial Projections:** Provide an overview of your financial projections, and how will you generate a return on this investment.

F. **Resources Requested:** Summarize the resources required to achieve your objectives, both internal and external. The matching funds and other amounts that will comprise the total budget for the project should be included in this section. The dollar amounts noted here should align with those in the Budget Justification section.

G. **Scope of Work and Milestones:** Provide an overview of the goals and objectives of the project. Define the key activities and anticipated milestones. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract.

H. **Key Personnel:** For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Describe the relevant experience of the management team in obtaining concrete results that are directly relevant to the proposed project.

   Key personnel are the principal investigator/project director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way. “Substantive” means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. “Measurable” means that they devote a specified percentage of time to the project. The indicated time is an obligatory

commitment, regardless of whether or not they request salaries or compensation. "Zero percent" effort or "TBD" or "as needed" are not acceptable levels of involvement for those designated as key personnel. While all participants that meet these criteria should be identified as "key," it is expected that the number of key personnel will be kept to a minimum.

I. **Competitive Landscape:** Provide a clear discussion of the competitive landscape related to the project, including any companies/university laboratories working on similar projects; indicate which of these projects constitute the greatest competitive threat. Describe how the project compares with competitors, and indicate any potential opportunities for partnering with them.

J. **Intellectual Property:** Provide a concise discussion of the intellectual property issues related to the project and list any relevant issued patents and patent applications, along with their titles and dates they were filed/published/issued. In addition, list any licensing agreements that the company has signed that are relevant to this application.

K. **Patents:** List any relevant issued patents and patent applications. Please include the titles and dates the patents were issued/filed/published. List any relevant license agreements.

L. **Organizational Commitment to Texas:** Describe how CPRIT funding of the applicant's company would benefit the state of Texas. For example, describe how the company would create high-quality new jobs in the state and/or recruit out-of-state talent, and mention any Texas-based subcontractors and suppliers that would be used and any other unique, Texas-based resources that would be leveraged.

10.4.11. Biographical Sketches of Key Scientific Personnel (8-page maximum)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages and must use the "Product Development Programs: Biographical Sketch" template. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 10.4.10]).

10.4.12. Budget

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

- Each award mechanism allows for up to a 3-year funding program with an opportunity for renewal after the term expires. The budget must be aligned with the proposed milestones. Financial support will be awarded based upon the breadth and nature of the project proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.
- CPRIT considers equipment to be items having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. Equipment not listed in the applicant's budget must be specifically approved by CPRIT subsequent to the award contract.
- Texas state law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.
- The annual salary that an individual may receive under a CPRIT award for FY 2016 is $200,000. In other words, an individual may request salary proportional to the percentage effort up to a maximum of $200,000. Salary does not include fringe benefits. CPRIT FY 2016 is from September 1, 2015, through August 31, 2016.

  Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of $200,000. The salary cap may be revised at CPRIT's discretion.

The Budget Section is composed of 4 subtabs that must be completed:

A. **Budget for All Project Personnel:** Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project.

B. Detailed Budget for Year 1: This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Consultant Charges, Contractual (Subaward/Consortium), Research Related, or Other. Applicants will be required to itemize costs.

C. Budget for Entire Proposed Period of Performance: This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs for all subsequent years. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*.

D. Budget Justification: Please specify your CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds. Provide a compelling justification for the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. The budget must be aligned with the proposed milestones.

11. AWARD ADMINISTRATION

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

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

www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

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

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

Project Revenue Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement, which can be found at http://www.cprit.state.tx.us/ and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas state law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has $1.00 in matching funds for every $2.00 from CPRIT. Matching funds need not be in hand when the application is submitted. However, matching funds must be obtained before CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. CONTACT INFORMATION

13.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. **Before contacting the HelpDesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. In addition, for Frequently Asked Programmatic Questions, please go here and for Frequently Asked Technical Questions, please go here.**

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time
Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Product Development Program Senior Manager.

Tel: 512-305-7676

Email: Help@CPRITGrants.org

Website: www.cprit.state.tx.us