CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA C-15-ETRA-1

Bridging the Gap:

Early Translational Research Awards

Please also refer to the Instructions for Applicants document, which will be posted June 26, 2014

FY 2015

Fiscal Year Award Period

September 1, 2014 — August 31, 2015

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

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RFA VERSION HISTORY

Rev 05/23/14 RFA release

Rev 06/24/14 Added Section 13: Business Plan Requirement

Rev 06/26/14 Added the following sentence to the end of Section 4: Research Objectives

- Applicants who plan to perform IND-enabling studies should document that they have experience and proficiency in doing such studies.

1. ABOUT CPRIT

The State of Texas established the Cancer Prevention and Research Institute of Texas (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:

- Create and expedite innovation in the area of cancer research, 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.

2. EXECUTIVE SUMMARY

CPRIT fosters cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This Request for Applications (RFA) solicits applications for research projects addressing critically important needs related to the diagnosis, prevention, and/or treatment of cancer. The objective of this award is to "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development by funding advancement toward investigational new drug (IND) clearance or investigational device exemption (IDE) approval (See Section 3, Mechanism of Support) for the therapeutic, device, or diagnostic assay through activities up to and including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario. The work funded under this RFA must be deemed sufficiently robust such that successful completion would result in identification of a "lead" compound, assay, or device that, as a next stage, could be taken into full development in

compliance with International Conference on Harmonization (ICH) Guidelines and U.S. regulatory guidance documents and regulations. Applicants must identify a clear path of development consistent with the Target Product Profile outlined in the application. **Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism; a public or private company is not eligible.**

3. MECHANISM OF SUPPORT

The goal of awards made in response to this RFA is to fund innovative cancer research from target identification to "lead candidate" stage, according to a defined Target Product Profile, that projects a clear path to full commercial development. This award allows the opportunity to develop proof-of-principle data necessary to bring promising cancer research projects to lead stage in preparation for full commercial development according to Food and Drug Administration (FDA) regulations. Funding may be provided for intermediate steps according to established milestones (often referred to as "stage gates") consistent with those utilized by pharmaceutical/biotechnology therapeutic, diagnostic, and/or device companies for "target identification to lead" development (i.e., achievement of planned Target Product Profile [Draft Package Insert]) prior to full development activities. 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.

1. **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?
2. **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?
3. **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 I, Phase II, and Phase III 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:

1. **Absorption, distribution, metabolism, excretion (ADME),** including, but not limited to, relevant studies based on route of administration.
2. **Safety (studies as mandated by ICH Guidelines).**
3. **Biomarkers (assays) that potentially target specific patient populations** for clinical trials.
4. **Biomarkers (assays) that can serve as potential pharmacodynamic markers** of clinical activity during early clinical trials designed to demonstrate proof-of-concept.
5. **Proposed current Good Manufacturing Practice (cGMP)** (including estimated costs) that can be scalable from Phase I through Phase III. Include information if there are possible plans for formulation.

Successful applicants should be working in a research environment capable of supporting potentially high impact studies. Access to a clinical environment and interaction with translational cancer physician-scientists are highly desirable.

4. RESEARCH OBJECTIVES

Areas of interest include translational preclinical studies that establish proof-of-concept. A detailed preclinical development plan that demonstrates the translation of the preclinical work to the eventual clinical studies will be required.

The current trend strongly favors programs with a strong proof-of-concept that can be undertaken at an acceptable level of risk. Increasingly, this is taken as a clear preclinical

indication of a population subset or biomarker approach allowing selection of an enhanced patient population more likely to respond to the therapy.

Examples of fundable projects include those that incorporate the study of potential biomarkers of use for the clinic, such as biomarkers for selection of patients (e.g., tumors with mutations in EGFR, DDR2, BRAF) and/or biomarkers that can be utilized as pharmacodynamic end points (e.g., measurement of bone degradation products in preclinical animal studies and early clinical studies of treatment of bone metastases), tissue distribution, preliminary stability or other "drugability" criteria or safety pharmacology studies conducted in compliance with ICH Guidelines and, thus, usable in a formal FDA regulatory submission. Applicants who plan to perform IND-enabling studies should document that they have experience and proficiency in doing such studies.

5. FUNDING INFORMATION

Applicants may request a maximum of $2,000,000 in total costs over a period of 1 to 3 years. Exceptions to these limits may be requested if extremely well justified (See Section 10.4.9). Applications funded under this mechanism will not be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, *in vitro* and *in vivo* studies, and travel to scientific/technical meetings or collaborating institutions. Funding is also available to support Good Laboratory Practice (GLP), cGMP, Good Clinical Practice (GCP), and regulatory expertise; to provide access to specialized technical infrastructure; and to develop a level of oversight and management that may be beyond the reach and experience of those conducting the research.

Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5 percent of the total award amount.

6. KEY DATES

RFA

RFA release	May 23, 2014

Application

Online application opens	June 26, 2014, 7 a.m., Central Time
Application due	August 7, 2014, 3 p.m. Central Time
Application review	October 2014

Award

Award notification	November 2014
Anticipated start date	December 2014

7. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism.
- A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Commercialization Program.
- The Principal Investigator (PI) must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may submit only one application under this RFA during this funding cycle.
- A PI may resubmit an application that was previously not funded (See Section 8). However, such a submission will consume the institution's quota.
- Because this award mechanism is intended to support research directed by a single investigator, only one Co-Principal Investigator (Co-PI) may be included. Collaborators should have specific and well-defined roles.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- **This award mechanism should not be used for clinical-stage development programs.** In such instances, the Individual Investigator Research Award, Multi-Investigator

Research Award, or Product Development Program award mechanisms are more suitable alternatives to this Early Translational Research Award mechanism.

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

8. RESUBMISSION POLICY

Since the Early Translational Research Awards is a new award mechanism in the Product Development Program, resubmissions are not available under this RFA. Any previously unfunded application may be submitted as a new application under this mechanism.

9. APPLICATION REVIEW

9.1. Review Process Overview

All eligible applications will be reviewed using a two-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Product Development Review Council. In the first stage, applications will be evaluated by an independent review panel consisting of scientific reviewers who have extensive experience with the business and entrepreneurial aspects of the pharmaceutical and biotechnology industries as well as advocate reviewers. Applications will be assessed for both scientific merit and commercial potential, including underlying intellectual property, perceived developmental path to market, and regulatory and market assessments. Committees will pay particular attention to the approach being proposed and the likelihood that the project will be positioned to attract other funding at program completion. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Product Development Review Council based on comparisons with applications from all of the peer

review panels and programmatic priorities. Applications approved 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. 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 703.6–703.8.

9.1.1. 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 Web site. **By submitting a grant application, the applicant agrees and understands that the only basis for consideration 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.

9.2. Review Criteria

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

9.2.1. Primary Criteria

Primary criteria will evaluate the scientific and commercial merit of the proposed work and the ability of this work to translate to the intended clinical scenario 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.

Impact and Responsiveness to RFA: Does the applicant's research support a feasible approach to an unmet cancer need? Is the application innovative? Does the project develop or capitalize on state-of-the-art technologies, methods, tools, or resources for cancer treatment or address important underexplored or unexplored areas that have application to the clinic? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Will the results of this research, if successful, position the lead of interest such that it can compete successfully for private sector funding?

Research and Development Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined plan for acquiring proof-of-principle data that can be translated to the clinic? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Competitive Landscape/Intellectual Property: Are you aware of the competitive landscape related to your project? Has the regulatory pathway been adequately described? Have intellectual property issues been addressed?

Applicant Investigator: Does the applicant demonstrate the required creativity, expertise, experience, and accomplishments to make a significant contribution to cancer research? Applicants' credentials will be evaluated in a career stage–specific fashion. Have early career–stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer treatment and application to the clinic? This will be an important criterion for evaluation of projects for CPRIT support.

9.2.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research. Secondary criteria include the following:

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

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, is certification of approval in place by the institutional IACUC and/or IRB, as appropriate? This certification will be required before funding can occur.

Budget: Is the budget appropriate and reasonable for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. SUBMISSION GUIDELINES

10.1. Institutional Limit

Because a large number of submissions is anticipated and to ensure timely and high-quality review of the most innovative and cutting-edge early translational research, CPRIT is imposing a limit on the number of applications that may be submitted by an institution during this review cycle. CPRIT expects institutions to **initiate an internal review process** and authorize submission of only those applications that have been rigorously judged to be responsive to this RFA. Institutional limits are as follows: University of Texas M. D. Anderson Cancer Center, six; Baylor College of Medicine, six; University of Texas Southwestern Medical Center, six; University of Texas Health Science Center at San Antonio, four; University of Texas Health Science Center at Houston, 4; University of Texas at Austin, four; University of Texas Medical Branch, four; Texas A&M University, four; Texas A&M University Health Science Center, four; Texas Tech University, four; Texas Tech University Health Sciences Center (combined campuses), four; all others, two each.

10.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Applications will be accepted beginning at 7 a.m. Central Time on June 26, 2014, and must be submitted by 3 p.m. Central Time on August 7, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.3. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

10.4. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions or Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing one or more components or do not meet the eligibility requirements listed in Section 7 will be administratively withdrawn without review.

10.4.1. Application Signing Official (ASO)

The ASO is an individual authorized to submit an application on behalf of an organization. An ASO must be identified and assigned to the application by the PI. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. The ASO must also create a user account in the online application receipt system.

10.4.2. Grants Contract/Office of Sponsored Projects Official

The Grants Contract/Office of Sponsored Projects official is the individual who will manage the grant if an award is made. This individual must be identified and assigned to the application either by the PI or by the ASO. The Grants Contract/Office of Sponsored Projects official must also create an ASO-type user account in the online application receipt system.

10.4.3. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Clearly address how the proposed project, if successful, will have a major impact on 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 (2,000 characters)

Provide a Layperson's Summary of the proposed work. Describe in very simple, nontechnical terms the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on improving the treatment of cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if

the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (Section 9.1) in evaluating the significance and impact of the proposed work.

10.4.5. Goals and Objectives (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 (One page)

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

10.4.7. Research and Development Plan (Ten pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

10.4.8. Vertebrate Animals and/or Human Biological Samples (One page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human biological samples will be used, provide a plan for acquisition of samples that will meet the time constraints of this award mechanism. Human/clinical trials are not permitted under this award mechanism.

10.4.9. Competitive Landscape/Intellectual Property (Five pages)

Complete the Competitive Landscape/Intellectual Property Plan using the template provided on the CPRIT Application Receipt System. Provide a clear discussion of the competitive landscape related to your project, including any companies/university laboratories working on similar projects; indicate which of these projects constitutes the greatest competitive threat. Describe the regulatory pathway for this project and any issues that may arise. Provide a concise discussion of the intellectual property issues related to your project and list any relevant issued patents and patent applications, along with their titles and dates they were issued/filed/published.

10.4.10. Publications/References

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

10.4.11. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Also state and justify if funds are requested to support expertise in regulatory issues, to provide access to specialized technical infrastructure, and/or to develop a level of oversight and management that may be beyond the reach and experience of those conducting the research. Applicants are advised NOT to interpret the maximum allowable request under this award as an invitation to expand the budget to this level. Reasonable budgets clearly work in favor of the applicant. However, if there is a highly specific and defensible need to request more than $2,000,000 (total funds), applicants should include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will have a negative impact on the overall evaluation of the application.

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

- Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent 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. So-called grants management and facilities fees (e.g., sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

- The maximum annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2015 is $200,000; CPRIT FY 2015 is from September 1, 2014, through August 31, 2015. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

10.4.12. Biographical Sketches (Two pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

10.4.13. Current and Pending Support

State the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a two-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided.

10.4.14. Institutional/Collaborator Support and/or Other Certification (Four pages)

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

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 703.10–703.12.

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.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must

be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. BUSINESS PLAN REQUIREMENT

Award recipients will be required to prepare and submit a business plan to CPRIT in the first year of the grant. The plan will be read and critiqued by CPRIT's Product Development Reviewers. It may be returned for rewriting if significant deficiencies are noted. At a minimum, the plan should include the following:

- A quantitative description of the market opportunity for the product.
- A discussion of the intellectual property protecting the product (professional patent searching and freedom to operate opinions are not required. The recipient should, however, show awareness of related or problematic intellectual property that might reasonably be discovered in a Google search and keyword search on the USPTO and WIPO websites).
- A description of the steps (including their time and cost) necessary for product development, clinical testing, and regulatory approval.
- A market strategy, including timeline and evaluation of competitive products and potential business partners. Pricing and product distribution channels should be discussed. This discussion should show an understanding of the potential customer and how purchasing decisions are made.
- Financial projections of the amount of cash needed by the business and how it will be used to reach product development milestones. Included here on a *pro forma* basis whould be estimates of: gross margins, net income, expenses, cash flows, and balance sheet. Broad categories with rough estimates for such items as "Administrative" and "Marketing" are acceptable.
- A description of the management and product development teams.
- A compelling executive summary.

The quality of the final business plan should be at a level that it could reasonably be submitted for consideration to venture capital sources.

14. CONTACT INFORMATION

14.1. HelpDesk

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

Dates of Operation: June 26, 2014, to August 7, 2014 (excluding public holidays)

Hours of Operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m., Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

14.2. Scientific and Programmatic Questions

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

Tel: 512-305-8486

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us