CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-17.1-ETRA

Early Translational Research Awards

Please also refer to the Instructions for Applicants document, which will be posted March 21, 2016

Application Receipt Opening Date: March 21, 2016

Application Receipt Closing Date: May 19, 2016

FY 2017

Fiscal Year Award Period

September 1, 2016-August 31, 2017

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 02/19/16 RFA release

Rev 02/22/16 Section 4 – Funding Information: Hyper-link was updated

1. ABOUT CPRIT

The state of Texas has 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 do the following:

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

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific 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. The program priorities for research adopted by the Oversight Committee include funding projects that address the following:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Building infrastructure.

2. RATIONALE

Early Translational Research Awards (ETRAs) are intended to support the development of preclinical studies that establish proof of concept. The current trend in funding by the private sector strongly favors programs with a solid proof of concept that can be undertaken at an

acceptable level of risk. Increasingly, for new treatments, this is taken as a clear preclinical indication of a population subset or biomarker approach allowing preselection of the patient population more likely to respond to the therapy.

Examples of appropriate projects for the RFA include those that incorporate the study of potential biomarkers of use for the clinic, such as biomarkers for selection of patients (eg, tumors with mutations in EGFR, DDR2, BRAF) and/or biomarkers that can be utilized as pharmacodynamic end points (eg, 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 International Conference on Harmonization (ICH) Guidelines and, thus, usable in a formal Food and Drug Administration (FDA) regulatory submission. Applicants who plan to perform investigational new drug (IND)-enabling studies should document that they have experience and proficiency in doing such studies. A detailed preclinical development plan that demonstrates the translation of the preclinical work to the eventual clinical studies will be required.

3. RESEARCH OBJECTIVES

CPRIT fosters cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This 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 IND clearance or investigational device exemption approval 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 ICH Guidelines and US regulatory guidance documents and regulations. Applicants must identify a clear path of development consistent with the Target Product Profile outlined in the application.

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 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 (ie, 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 diagnosis or treatment of cancer?
(2) Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential 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 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:

- Absorption, distribution, metabolism, excretion (ADME), 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 (cGMP) (including estimated costs) that can be scalable from phase 1 through phase 3. 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. FUNDING INFORMATION

Applicants may request a maximum of $1,000,000 in total costs over a period of 1 to 3 years. Exceptions to this limit may be requested if extremely well justified (see section 8.3.7). 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, cGMP, good clinical practice, 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% of the total award amount.

5. 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 Product Development Program.

- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, 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 1 application under this RFA during this funding cycle.
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-Principal Investigator (Co-PI) may be included.
- Collaborations are permitted and encouraged, and there should be specific and well-defined roles. 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 12 and section 13. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

CPRIT has determined that since this round of the ETRAs is set up as a new award mechanism under the Academic Research program, resubmissions are not available under this RFA. All projects eligible for resubmission should be submitted as new applications for this cycle.

An ETRA application that was unfunded after a single review under Product Development should be submitted as a new application under this RFA. However, if a summary statement was prepared for the original application review, applicants are advised to address all noted concerns. Applications that received overall numerical scores of 5 or higher are likely to need considerable

attention. All previously unfunded ETRA submissions should be carefully reconstructed and take reviewers comments under consideration when submitting a new application.

7. RENEWAL POLICY

Renewals are not available under this RFA.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. The Co-PI does not have to create a user account in CARS; the Co-PI will be added to the application by the PI. Please refer to the *Instructions for Applicants (IFA)* document for the instructions on adding Co-PIs to an application. The IFA document will be available when the application receipt system opens. Applications will be accepted beginning at 7 AM central time on March 21, 2016, and must be submitted by 3 PM central time on May 19, 2016. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of extenuating circumstances. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of 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. Please note that deadline extension requests are very rarely approved.

8.2. 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 IFA document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 5 will be administratively rejected without review.

8.2.1. 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.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

8.3. Layperson's Summary (5,000 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 9.2) in evaluating the significance and impact of the proposed work.

8.3.1. Goals and Objectives

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.

8.3.2. Timeline (1 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.

8.3.3. Research and Development Plan (10 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.

8.3.4. Vertebrate Animals and/or Human Biological Samples (1 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.

8.3.5. Competitive Landscape/Intellectual Property (5 pages)

Complete the Competitive Landscape/Intellectual Property Plan using the template provided in CARS. 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.

8.3.6. Publications/References

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

8.3.7. 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 $1,000,000 (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% 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. So-called grants management and facilities fees (eg, 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 2017 is $200,000; CPRIT FY 2017 is from September 1, 2016, through August 31, 2017. 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.

8.3.8. Biographical Sketches (5 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 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 5 pages. The NIH Biosketch format is appropriate.

8.3.9. 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 2-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.

8.3.10. Institutional/Collaborator Support and/or Other Certification (4 Pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.3.11. Institutional Limits

Because a large number of submissions is anticipated, and to ensure timely and high-quality review of the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, CPRIT is imposing a limit on the number of ETRA applications that may be submitted by an institution during this review cycle.

The limit on the number of applications may seem restrictive, but experience indicates that truly innovative ideas that are appropriate for this award mechanism are uncommon. CPRIT expects institutions to initiate an internal review process and only authorize submission of the appropriate number of applications that have been rigorously judged to be responsive to this RFA. Institutional limits (which need not be fully used) are as follows: The University of Texas M. D. Anderson Cancer Center, 10; Baylor College of Medicine, 10; The University of Texas

Southwestern Medical Center, 10; The University of Texas Health Science Center at San Antonio, 10; The University of Texas Health Science Center at Houston, 10; The University of Texas at Austin, 10; The University of Texas Medical Branch, 10; Texas A&M University, 10; Texas A&M University Health Science Center, 10; Texas Tech University, 10; Texas Tech University Health Sciences Center, 5; Texas Tech University Health Sciences Center at El Paso, 5; all other academic research institutions, 5 each.

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

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Peer Review panel members for scientific soundness, impact, and potential for commercial development.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, Biographical Sketches, and Competitive Landscape/Intellectual Property. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer diagnosis or therapy and limited commercial potential and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent

peer review panel consisting of scientific and commercialization experts as well as advocate reviewers using the criteria listed below. 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 Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific 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 to 703.8.

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

9.3. Confidentiality of Review

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

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific 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 grant applicant (or someone on the grant applicant's behalf) and the following individuals: An

Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services.

The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period prior to the opening of CARS. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review panels 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 merit and feasibility of commercialization of each application is within the sole discretion of the peer reviewers.**

9.4.1. 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 outcome 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 of Overall Program: 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: Is the applicant aware of the competitive landscape related to the 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 and product development? 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 of Project: Does the proposed research have a high degree of relevance to cancer prevention, detection, or treatment? These will be important criteria for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

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

Research Environment: Does the team have the needed expertise, facilities, and resources to accomplish all aspects of the project? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support for 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, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

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

10. 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 would 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.

11. KEY DATES

RFA

RFA release February 19, 2016

Application

Online application opens	March 21, 2016, 7 AM central time
Application due	May 19, 2016, 3 PM central time
Application review	June – September 2016

Award

Award notification	November 2016
Anticipated start date	December 2016

12. AWARD ADMINISTRATION

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

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

13. 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 regarding demonstration of available funding.

14. CONTACT INFORMATION

14.1. 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 aspects of applications.

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

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 Senior Program Manager for Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.state.tx.us