CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA R-19.2-ETRA

Early Translational Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on October 17, 2018

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

Application Receipt Opening Date: October 17, 2018

Application Receipt Closing Date: January 30, 2019

FY 2019

Fiscal Year Award Period

September 1, 2018-August 31, 2019

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RFA VERSION HISTORY

Rev 08/17/18 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $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 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. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing 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 between and within the agency's Academic Research, Prevention, and Product Development Research programs as well as guide CPRIT staff and Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Funding early translational research, which bridges the gap between basic research and product development, has been identified by CPRIT's Oversight Committee as a CPRIT priority for strategic investment. Data indicate that translational research is underfunded and would benefit from additional investment to translate new discoveries into practical advances for cancer patients. Funding research and product development at this early stage would have the added benefit of stimulating public-private partnerships and bringing new commercial investments to Texas.

2. RATIONALE

CPRIT's Academic Research and Product Development Research programs have established 2 new RFA mechanisms aimed at the development of innovative technologies at Texas research

institutions that demonstrate great promise to impact the cancer burden in Texas and elsewhere. The Early Translational Research Award (ETRA) described in this RFA and the companion Seed Funding Award mechanism by CPRIT's Product Development Research program are being offered to fund the development of therapeutics, devices, or diagnostic assays designed to lessen the burden of cancer. The aim of these awards is to narrow the funding gap (sometimes referred to as the "valley of death") for the preclinical development of oncology products and to address the need for involvement of business expertise early in the preclinical product development stages. The overall goal of these mechanisms is to create a pipeline of promising new cancer products developed by the Texas bioscience community and to advance successful technology commercialization and company development.

3. RESEARCH OBJECTIVES

The ETRA is intended to bridge the gap between promising new discoveries achieved in the research laboratory and the commercial development of a therapeutic product, medical device, or diagnostic assay through activities up to and including preclinical proof-of-concept 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 a lead product that has compelling evidence of efficacy in qualified models, a favorable preliminary safety profile, and, for therapeutics, evidence of feasibility of scale-up and bulk synthesis. In other words, at the completion of the project it will be clear if the lead product under development has the attributes necessary to attract private investment to continue its development toward IND-enabling studies (IDE-enabling preclinical plan in the case of a medical device) and clinical evaluation.

Applicants are advised that the ETRA mechanism is designed to initiate the product development process for a promising technology that has a novel target and/or promises to address an unmet clinical problem and to move its development toward an investible technology and business opportunity. Typically, applicants for the ETRA award will have completed target validation; for therapeutics, they will have identified early hits; and for a novel device, they will have developed a prototype concept; and for a diagnostic, they will have identified a prototype test. Basic discovery research designed to identify or validate a new target or to support exploratory screening for new hit generation is not responsive to this RFA.

Applicants are required to demonstrate the engagement of their institution's technology transfer

office or equivalent early in the process for development of a comprehensive business plan that will consider clinical utility, target market, and how intellectual property will be protected. This plan should include a target product profile (TPP) that documents the path of product development and includes "go/no go" decision points or milestones (often referred to as "Stage gates") consistent with those utilized by pharmaceutical/biotechnology therapeutic, diagnostic, and/or device companies for lead development.

3.1. Successful ETRAs

By the completion of the funding period, a successful ETRA will have:

- Identified a novel therapeutic or diagnostic technology and shown a biological effect;
- Convincing, statistically significant, and reproducible disease-modifying activity with applicable controls in a relevant preclinical model(s) that is comparable or better than standard-of-care therapy;
- Conducted preliminary safety and toxicology testing (in the case of therapeutic agents);
- Shown the product can be manufactured at small scale or as a prototype;
- Shown for a diagnostic test that the analyte(s) can be measured at biologically relevant levels;
- Assessed the business opportunity addressing key issues (clinical utility, target market, financial plan, IP strategy, technical challenges, etc) and a development plan addressing key issues going forward toward clinical testing (eg, formulation, toxicology, scale-up, pre-IND development, clinical trials, regulatory pathway, etc);
- Initiated a patent application.

3.2. ETRA mechanism activities

Examples of activities appropriate for the ETRA mechanism include the following (note this list is specific to therapeutics and not intended to be exhaustive):

- Lead optimization and identification of alternative lead series;
- Synthesize the optimized lead for *in vivo* efficacy, toxicity, and PK/PD assessments;
- Evaluate activity in relevant preclinical models and demonstrate statistically significant, reproducible disease activity;

- Evaluate structure-activity relationships as related to disease specificity, potency, or formulation issues;
- Evaluate biopharmaceutical properties (absorption in rodents and nonrodents, clearance, and bioavailability);
- Assess preliminary preclinical assessment completed of dose, safety profile, therapeutic window, formulation, and stability;
- Assess preclinical toxicology, PK, and PD assessments;
- Evaluate biodistribution;
- Evaluate clinical readiness of PK/PD assay(s) and specimen handling SOPs;
- Evaluate preliminary safety issues in range-finding toxicology studies;
- Assess feasibility of scale-up and bulk synthesis;
- Assess amenability to imaging;
- Market research and physician input into product design;
- Competitive evaluation.

3.3. Development of medical devices and diagnostic technologies specific to cancer

The ETRA program also supports development of medical devices and diagnostic technologies specific to cancer. Examples of activities appropriate for the ETRA mechanism for device and diagnostic technologies include the following:

- System design, development, prototype fabrication, and laboratory testing;
- Functional *in vitro* testing;
- Functional *in vivo* testing in relevant animal models;
- Toxicology and biocompatibility testing;
- Biomarker assessment in the clinical setting;
- Safety testing and failure modes analysis;
- Market research and physician input into product design;
- Competitive evaluation.

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.

IMPORTANT: The application must demonstrate the engagement of an institution's technology transfer office or equivalent expertise to provide the business guidance needed to ensure that intellectual property issues are addressed and that a strategic plan for development and the eventual commercialization of the research is in place. Applicants are encouraged to identify a Co-Principal Investigator (Co-PI) with business acumen to provide this guidance.

4. FUNDING INFORMATION

The maximum duration for this award mechanism is 2 years. Applicants may request up to $2,000,000 in total costs over a period of 1 to 2 years. Exceptions to this limit may be requested if extremely well justified (see section 8.2.10).

- 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;
- Funds may be requested for salary and fringe benefits to support a Co-PI with the business expertise to aid in completing market analysis, business plans, and product development strategies;
- Note the annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award is limited to a maximum of $200,000. In other words, an individual may request salary proportional to the percent of effort up to a maximum of $200,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.
- Funding is also available to support access to good laboratory practice, good clinical practice, and regulatory expertise and to provide access to specialized technical infrastructure and provide access to expertise that may be beyond the reach and experience of those conducting the research;

- Requests for funds for research services outsourced on a contract basis to a contract laboratory services organization are appropriate if the need is well documented, justified, and cost effective.
- Note that when considering contracting for consultants or contract services that are located outside of Texas, it is the policy of the Institute to encourage the purchase of goods and services required for the grant award from suppliers in Texas to the extent reasonably possible. A grant recipient is expected to undertake good faith efforts to purchase or contract with research service organizations and consultants from suppliers in Texas for at least 50% of the goods and services purchased with grant award funds. (see Chapter 701, section 701.21)
- Because of the nature of this funding mechanism, renewal applications will not be accepted.
- 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. However, CPRIT is imposing a limit on the number of ETRA applications that may be submitted by an institution during this review cycle (see section 8.2.14). 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 Co-PI who has experience in managing relevant translational programs and will contribute to the development and implementation of an integrated strategic business and technology development plan is strongly encouraged.

- A PI may submit only 1 application under this RFA during this funding cycle. Only 1 Co-PI may be included. The Co-PI must reside in Texas for the period of the time that the research that is the subject of the grant is conducted.
- A Co-PI may participate on multiple applications under this RFA during this funding cycle.
- Specific and well-defined 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 except as noted in the next bullet point.
- Research services outsourced on a contractual basis to a contract laboratory services organization or a paid consultant are appropriate if the need is well documented, justified, and demonstrated to be cost effective. Contract laboratory services organizations or paid consultants not located in Texas are eligible (note earlier reference to Chapter 701, section 701.21).
- An individual may serve as a PI on no more than 3 active Academic Research grants. Recruitment Grants and Research Training Awards do not count toward the 3-grant maximum; however CPRIT considers project leaders on a MIRA award equivalent to a PI. For the purpose of calculating the number of active grants, CPRIT will consider the number of active grants at the time of the award contract effective date (for this cycle expected to be 8/31/19).
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.

- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, 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.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

6. RESUBMISSION POLICY

The Early Translational Research Award is set up as a new award mechanism. Resubmissions are not available under this RFA.

An ETRA application that was unfunded after a single review under the Academic Research or Product Development Programs may 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.

7. RENEWAL POLICY

Renewals are not available under this RFA. A previously funded ETRA may be submitted as a new application under this mechanism.

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 Application Signing Official (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 October 17, 2018, and must be submitted by 4 PM central time on January 30, 2019. **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 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 within 24 hours of the submission deadline. 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 withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly describe your technological innovation and its impact on cancer burden. Discuss the current stage of the innovation or new product's development and what is necessary to move the innovation or product toward commercial development. Identify key steps that will be necessary to launch a startup venture for commercializing the innovation or new product.

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe in 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.

8.2.3. 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.

8.2.4. 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.

8.2.5. Research and Development Plan (10 Pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer that will be addressed and documenting that the project is ready for this development stage.

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 aims and demonstrate that the program is ready to begin lead product development stage are a critical component of this section. For example, in the case of a therapeutic product development, there must be sufficient evidence that the project is positioned to identify and validate a lead compound. Basic discovery research designed to identify or validate a new target or to support exploratory screening for new hit generation is not responsive to this RFA.

Discuss the major product development milestones to be achieved with funding. Indicate the time when each milestone is to be achieved and the investigator responsible for achieving it (PI, and if applicable Co-PI). Where appropriate, describe plans to utilize technical expertise on a contract basis and/or specific services from a contract laboratory services organization or similar entity to achieve these milestones and move the product's development forward. Discuss how the project will implement "go/no go" decisions based on these milestones.

8.2.6. Vertebrate Animals and/or Human Biological Samples (2 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.

8.2.7. Business Plan (5 pages)

Critical elements of this plan should include a market assessment, plans to protect relevant intellectual property, and preparation of a preliminary TPP. 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.

8.2.8. Letter of Support from the Chief Technology Transfer Officer or equivalent (1 page)

Provide a letter signed by the institution's Chief Technology Transfer Officer or equivalent that documents the selection process used to identify the application(s) for submission to CPRIT and documents the institution's commitment to proving guidance as the project moves forward along the development pipeline.

8.2.9. Publications/References

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

8.2.10. Budget and Justification

Provide a justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, animal care costs, and other expenses. If contractual services from a contract laboratory services organization not located in Texas are planned, these must be justified as not available from a Texas-based entity and/or more cost effective. 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% 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.texas.gov. 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 administratively withdrawn and returned without review.
- Note the annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award for FY 2019 is limited to a maximum of $200,000. In other words, an individual may request salary proportional to the percent of effort up to a maximum of $200,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. 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 recommended.

8.2.12. 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.

8.2.13. 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.

8.2.14. Institutional Limits

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) prior to preparation of the application. These limits are based upon an institution's past success at obtaining CPRIT and/or NIH research funds.

Institutional limits (which need not to be fully used) are as follows: Baylor College of Medicine (3), The University of Texas M. D. Anderson Cancer Center (3), The University of Texas Southwestern Medical Center (3), Methodist Hospital Research Institute (2), Rice University (2), Texas A&M University (includes: Agrilife Research; Engineering Experiment Station) (2), The University of Texas at Austin (2), The University of Texas Health Science Center at Houston (2), The University of Texas Health Science Center San Antonio (2), Texas A&M University Health Science Center (2), Texas Tech University Health Sciences Center (2), The University of Texas Medical Branch Galveston (2), University of Houston (2), all others (1).

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 withdrawn without review.

8.3. Formatting Instructions

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English.
- **Document Format:** PDF only.
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Line Spacing:** Single.
- **Page Size:** 8.5 x 11 inches.
- **Margins:** 0.75 inch, all directions.
- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.
- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. Include URLs of publications referenced in the application.

  Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135: 45–67.
- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

9. APPLICATION REVIEW

9.1. Review Process Overview

All eligible applications will be evaluated using a 2-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council (SRC). In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific and oncology product development experts as well as advocate reviewers using the criteria provided in the link 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 SRC based on comparisons with applications from all the peer review panels and programmatic priorities. Applications approved by SRC will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the CPRIT Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote on whether 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. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Academic Research Peer Review Panel members, Academic Research SRC 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 Academic Research Peer Review Panel members and Academic Research 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, an Academic Research Review Panel member, or an Academic Research 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.

9.3. 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.**

9.3.1. Primary Criteria

Primary criteria will evaluate the scientific and commercial merit (market opportunity and competitiveness) of the proposed work and the ability of this work to translate to a significant improvement over current standard of care or current solution in market. Concerns with any of

these criteria potentially indicate a major flaw in the significance and/or design of the proposed study.

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? Will the results of this project, if successful, position the oncology product of interest such that it can compete successfully for private sector funding to continue advancement to clinical study?

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? Are the proposed milestones and the expected project outcome likely to be achieved within the proposed timeline?

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 (percent 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.

9.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed 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 biological samples are included in the proposed research, is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed? Note that 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. KEY DATES

RFA

RFA release	August 17, 2018

Application

Online application opens	October 17, 2018, 7 AM central time
Application due	January 30, 2019, 4 PM central time
Application review	February 2019 to August 2019

Award

Award notification	August 21, 2019
Anticipated start date	August 31, 2019

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. 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.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in 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 documented in the grant award contract and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate.

CPRIT will review annual progress reports and continuation of funding is contingent upon the timely receipt of these reports and documentation of sufficient progress toward completing project goals. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Progress reports that fail to document progress toward completion of project goals or failure to achieve key project milestones (Stage gates) will result in an early termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

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

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

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Program Manager for Academic Research.

Tel: 512-305-8491
Email: Help@CPRITGrants.org
Website: www.cprit.texas.gov