CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-18.1-IIRACT

Individual Investigator Research Awards for Clinical Translation

Please also refer to the Instructions for Applicants document, which will be posted on March 15, 2017

Application Receipt Opening Date: March 15, 2017

Application Receipt Closing Date: June 8, 2017

FY 2018

Fiscal Year Award Period
September 1, 2017-August 31, 2018

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RFA VERSION HISTORY

Rev 1/05/17 RFA release

Rev 3/15/17 Revised Section 5 (Eligibility): Role of MIRA project leader clarified to help calculate number of concurrent CPRIT grants a PI can hold. Revised Section 8 (Responding to this RFA – Subsection 8.1.1): Submission deadline extension language revised to comply with CPRIT's Administrative Rule.

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. Academic 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 with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas (lung, liver, cervix cancers)

2. RATIONALE

This Individual Investigator Research Awards for Clinical Translation (IIRACT) mechanism will support the conduct of hypothesis-based studies of novel cancer therapies or devices in early-phase clinical trials or completed trials where the outcome is known. Such clinical trials offer important opportunities to incorporate biomarkers, pharmacokinetic and pharmacodynamic monitoring, and/or imaging studies to provide more precise knowledge about what works, in whom, and in which types of cancer and to guide subsequent clinical development of a novel cancer therapy.

The research supported by this mechanism is important because current clinical development of novel cancer therapeutics remains slow and expensive with many late-stage failures. Only 5% of cancer therapeutics that enter clinical evaluation will be approved, and the approval process is often measured in decades. There is an urgent need to accelerate and enhance the efficiency of this process by improving the clinical evaluation of novel cancer therapeutics through adoption of modern trial designs that incorporate biomarkers. Such trials will build on advances in basic discovery that have identified the critical targets involved in the hallmarks of cancer and have led to mechanism-based therapeutics. Trials that are designed to determine if predictors of response and efficacy identified in preclinical models also occur in patients have the potential to accelerate therapeutic development and approvals. They also guide the development of diagnostic tests to identify those patients most likely to benefit from these new treatments. Well-conducted early-phase studies will also inform reasons for treatment failure and feed back to preclinical studies designed to overcome barriers to success identified in patients.

3. RESEARCH OBJECTIVES

The goal of the IIRACT Award is to promote clinical research that will lead to a better understanding of the clinical efficacy of a cancer therapy or diagnostic device. Applications submitted under this mechanism should propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known.

Clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices are all responsive to this Request for Applications (RFA).

Applications that propose the development and validation of a biomarker (biospecimen derived from patient tissue or biofluid) or an imaging biomarker are responsive to this RFA provided that the research plan includes validation steps that involve patients treated on a clinical trial.

Early-phase clinical trials of agents or combinations of agents for which there are robust nonclinical data that suggest there may be clinical activity are responsive to the RFA, even if there is no biomarker, as long as the early-phase clinical trial will lead to determining if the activity observed in the laboratory can be replicated in patients.

Additional examples of the types of studies appropriate for the IIRACT award include, but are not limited to, the following:

- Exploratory, phase 1, or small phase 2 trials of new agents, repurposed agents, radiation therapy, surgery, or combinations of interventions where the trial design incorporates biomarker and/or imaging strategies to determine one or more of the following: presence of the drug target, target inhibition, biological pathway inhibition, or pathophysiological alteration by the investigational drug or device
- Discovery and/or validation of predictive biomarkers (eg, genomic, proteomic, or metabolomic signatures of response) using biospecimens from trials where the outcome is known
- Correlation of the activation of specific signaling pathways with clinical outcomes
- Pharmacogenomic studies aimed at the identification of genomic profiles associated with increased/decreased efficacy or toxicity during clinical interventions
- Discovery and/or early validation of biomarkers elucidating mechanisms of action of interventions aimed at preventing or treating symptoms and/or toxicities resulting from treatment using biospecimens from clinical trials where the outcomes are known
- Molecular analyses of biospecimens obtained from exceptional responders

4. FUNDING INFORMATION

- Applicants may request a maximum of $400,000 per year for a period of up to 3 years.
- Applicants who plan on conducting a clinical trial as part of the project may request up to $600,000 in total costs per year for up to 4 years.
- Exceptions to these limits may be requested if extremely well justified.
- If a clinical trial is proposed, the budget justification must include a timeline for trial initiation and accrual targets.
- If a clinical trial is proposed, applications should provide documentation that the proposed trial is feasible within the project timeline. For example, drug access through an industry or CTEP arrangement should be documented. When indicated an approved investigational new drug application (IND) or investigational device exemption (IDE) for devices from the Food and Drug Administration (FDA) should be cited, or if no IND is yet available for the agent(s), then a pre-IND meeting would have been held with the FDA, and the summary letter from that pre-IND meeting would be included as an attachment (see section 8.2.9).
- Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs including diagnostic or interventional procedures associated with participation in a clinical trial and not considered routine patient care, and travel to scientific/technical meetings or collaborating institutions (see section 8.2.11).

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization 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 Research 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 not submit applications to this RFA and to RFA-R-18.1-IIRA, RFA-R-18.1-IIRACB, RFA-R-18.1-IIRACCA, or RFA R-18.1-IIRAP. Only 1 IIRA, IIRACT, IIRACB, IIRACCA, or IIRAP application per cycle is allowed.
- A PI may be a Co-PI on applications submitted to this RFA and to RFA-R-18.1-IIRACB, RFA-R-18.1-IIRACCA, RFA R-18.1-IIRA, or RFA R-18.1-IIRAP.
- A PI may submit both a new application to this RFA and a renewal application to another RFA during this funding cycle.
- An individual may serve as a PI on no more than three active Academic Research grants. Recruitment Grants and Research Training Awards do not count toward the three-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 3/1/18).
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included.
- 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.
- 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 organization or institution 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

Because the Individual Investigator Research Awards for Clinical Translation mechanism is a new award mechanism, resubmission is not available under this RFA. If a previously unfunded IIRA, IIRAP, or IIRACCA application is responsive to the IIRACT RFA, it may be submitted as a new application under the IIRACT mechanism.

7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA, IIRACCA, or IIRAP that is appropriate for the IIRACT mechanism may be submitted under this RFA for a competitive renewal. See section 8.2.5. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See section 9.2.

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. The Co-PI, if applicable, must also

create a user account to participate in the 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. Applications will be accepted beginning at 7 AM central time on March 15, 2017, and must be submitted by 4 PM central time on June 8, 2017. **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 good cause. 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 *Instructions for Applicants* 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)

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. **Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (**see section 9.1**)**. 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).

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 cancer.

Summarize how the proposed research creates new paradigms or challenges existing ones.

Indicate whether this research plan represents a new direction for the PI.

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 advancing the field of cancer research, early diagnosis, prevention, or treatment. 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.

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 a clinical trial is proposed as a component of this application, the timeline must include clearly defined patient accrual milestones.

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. Renewal Summary (2 Pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and

manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.6. Research Plan (11 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. This section has been lengthened to allow the applicant to present the statistical considerations used to determine a trial design, accrual milestones, and biomarker validation.

8.2.7. Vertebrate Animals and/or Human Subjects (2 pages)

If vertebrate animals will be used, provide a detailed plan of the protocols that will be followed. If human subjects or human biological samples will be used, provide a detailed plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism. 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.

8.2.8. Protocol Documentation

If a clinical trial is planned, a PDF copy of the full protocol can be attached.

8.2.9. Investigational New Drug Application (IND)/Investigational Device Exemption (IDE)

If a clinical trial is proposed that requires an IND or IDE, provide evidence of an approved investigational new drug application (IND) or investigational device exemption (IDE) for devices from the Food and Drug Administration (FDA). If no IND is yet available for the agent(s), then provide a summary letter from a pre-IND meeting held with the FDA. If the drug or device is to be provided through an industry or CTEP mechanism, provide documentation that the drug or device will be available.

8.2.10. Publications/References.

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

8.2.11. Budget and Justification

Provide a compelling and detailed 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. The justification should include the statistical considerations that led to the clinical trial design, accrual milestones, and validation of biomarkers.

Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request.

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 rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2018 is $200,000; CPRIT FY 2018 is from September 1, 2017, through August 31, 2018. 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.

8.2.12. 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.

8.2.13. Current and Pending Support

Describe 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. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.14. 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.

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 Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. 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 research 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 experts as well as advocate reviewers using the criteria listed in section 9.4. Applicants will be notified of peer review panel assignments prior to the peer review meeting dates. Peer review panel membership can be found on the CPRIT website. 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.

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 Research 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 when preapplications or letters of interest are accepted. 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

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 merit of each application is within the sole discretion of the peer reviewers.**

9.4.1. Primary Criteria

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

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and expertise to make a significant contribution to the 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 (percent effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This is a critical criterion 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 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: Is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed?

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	January 5, 2017

Application

Online application opens	March 15, 2017, 7 AM central time
Application due	June 8, 2017, 4 PM central time
Application review	August-October 2017

Award

Award notification	February 14, 2018
Anticipated start date	March 1, 2018

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 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.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. A grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the 5% indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding. 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.

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 Manager for Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov