



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-16-MIRA-2

Multi-Investigator Research Awards

Please also refer to the “Instructions for Applicants” document, which will be
posted on August 11, 2015

Application Receipt Opening Date: August 11, 2015

Application Receipt Closing Date: October 13, 2015

FY 2016

Fiscal Year Award Period

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TABLE OF CONTENTS

| | |
|---|-----------|
| 1. ABOUT CPRIT | 6 |
| 1.1. RESEARCH PROGRAM PRIORITIES | 6 |
| 2. RATIONALE | 6 |
| 3. RESEARCH OBJECTIVES | 8 |
| 4. FUNDING INFORMATION | 9 |
| 5. ELIGIBILITY | 9 |
| 6. RESUBMISSION POLICY | 11 |
| 7. RENEWAL POLICY | 11 |
| 8. CHARACTERISTICS OF MULTI-INVESTIGATOR RESEARCH AWARDS | 11 |
| 8.1. SYNERGY | 11 |
| 8.2. LEADERSHIP..... | 12 |
| 8.2.1. Principal Investigator (PI)..... | 12 |
| 8.2.2. Co-Principal Investigator (Co-PI)..... | 12 |
| 8.3. RESEARCH PROJECTS | 12 |
| 8.4. CORE RESOURCES | 13 |
| 8.5. SELECTION OF RESEARCH PROJECTS AND CORE RESOURCES..... | 14 |
| 8.6. COMMITMENT OF TIME AND EFFORT | 14 |
| 8.7. PARTICIPATION ON MORE THAN 1 APPLICATION..... | 15 |
| 9. RESPONDING TO THIS RFA | 15 |
| 9.1. APPLICATION SUBMISSION GUIDELINES | 15 |
| 9.1.1. Submission Deadline Extension | 16 |
| 9.2. APPLICATION COMPONENTS | 16 |
| 9.2.1. Abstract and Significance (15,000 characters)..... | 16 |
| 9.2.2. Layperson’s Summary (10,000 characters)..... | 16 |
| 9.2.3. Goals and Objectives (Maximum of 3 Goals and 3 Objectives per Goal for Each Project and Core) 17 | |
| 9.2.4. Timeline (Maximum of 1 Page per Project and Core)..... | 17 |
| 9.2.5. Resubmission Summary (10 pages)..... | 17 |
| 9.2.6. Overview of Overall Program (10 Pages) | 18 |
| 9.2.7. Research Project Abstract (Maximum of 5,000 characters per Project)..... | 18 |
| 9.2.8. Research Project Plan (Up to 25 Pages for Each Project)..... | 18 |
| 9.2.9. Core Resource Abstract (Maximum of 5,000 characters per Core Resource)..... | 19 |
| 9.2.10. Core Resource Plan (Up to 25 Pages for Each Core Resource) | 19 |
| 9.2.11. Administrative Core Plan (5 Pages) | 20 |
| 9.2.12. Synergy Illustration (3 Pages)..... | 20 |
| 9.2.13. Vertebrate Animals and/or Human Subjects (5 Pages)..... | 20 |
| 9.2.14. Publications/References..... | 21 |
| 9.2.15. Budget and Justification..... | 21 |
| 9.2.16. Biographical Sketches for Key Personnel(5 Pages Each) | 22 |
| 9.2.17. Current and Pending Support | 22 |
| 9.2.18. Institutional/Collaborator Support and/or Other Certification (15 Pages)..... | 22 |
| 9.2.19. Previous Summary Statement..... | 23 |
| 10. APPLICATION REVIEW | 23 |
| 10.1. PRELIMINARY EVALUATION..... | 23 |
| 10.2. FULL PEER REVIEW | 23 |
| 10.3. CONFIDENTIALITY OF REVIEW | 24 |

10.4. REVIEW CRITERIA..... 25
 10.4.1. Primary Criteria..... 25
 10.4.2. Secondary Criteria..... 27
11. KEY DATES..... 27
12. AWARD ADMINISTRATION..... 27
13. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS..... 28
14. CONTACT INFORMATION..... 29
 14.1. HELPDESK..... 29
 14.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS 29

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RFA VERSION HISTORY

Rev 07/06/15 RFA release

Rev 07/20/15 Revised Section 11 - Key Dates

- Corrected Application due date time from 11:59 PM central time to 3 PM central time

Rev 09/03/15 Revised Section 9.2.5- Resubmission Summary

- Increased page limit from 1 to 10 pages

Revised Section 9.2.8 – Research Project Plan

- Increased page limit from up to 20 to up to 25 pages
- Increased page limit of “Biographical Sketches” from 2 pages to a maximum of 5 pages.
- Replaced “Appropriate templates will be provided in CARS” with “The NIH Biosketch format is appropriate”
- Added “Vertebrate Animals and/or Human Subjects” section and description
- Added clarification to the Budget and Justification description

Revised Section 9.2.9 – Core Resource Plan

- Increased page limit from up to 20 to up to 25 pages
- Increased page limit of “Biographical Sketches” from 2 pages to a maximum of 5 pages.
- Replaced “Appropriate templates will be provided in CARS” with “The NIH Biosketch format is appropriate”
- Added “Vertebrate Animals and/or Human Subjects” section and description
- Added clarification to the Budget and Justification description

Revised Section 9.2.11 – Administrative Plan

- Changed title of the section from “Administrative Plan” to “Administrative Core Plan”

Revised Section 9.2.13 – Vertebrate Animals and/or Human Subjects

- Revised language to indicate that information should be incorporated into this section only if the applicant needs to include information not covered in the Research Project and /or Core Resource plans.

Revised Section 9.2.16 – Biographical Sketches

- Changed section title from “Biographical Sketches” to “Biographical Sketches for Key Personnel”
- Increased limit of individual biographical sketches from 2 to 5 pages
- Added language to indicate that the NIH Biosketch format is appropriate

Revised Section 9.2.18 – Institutional/Collaborator Support and/or Other Certification

- Increased page limit from 4 to 15 pages

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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
- Infrastructure development

2. RATIONALE

Multi-Investigator Research Awards are intended to support the creation of integrated programs of collaborative and cross-disciplinary research among multiple investigators. These should be equivalent to program projects, research centers, NCI SPOREs, multi-institutional clinical trial

networks, or other types of collaborative interactions. Teams will focus on critical areas of cancer research, especially those that have been inadequately addressed by research up to this point or for which there may be an absence of an established paradigm or technical framework. Laboratory research, translational studies, clinical, and population-based investigations may be supported. Awards are expected to promote a cooperative environment that fosters intensive interaction among members in all aspects of the research program. This approach is expected to transform the research process through the integration of basic and/or clinical disciplines, leading to the aggressive translation of scientific discoveries into tools and applications that have the potential to make a significant impact on cancer incidence, detection, treatment, and/or survivorship.

While all investigators need not be trained specifically in cancer research, this award is intended to initiate sustainable, collaborative programs of cancer research that cannot be addressed effectively by an individual researcher or a group of researchers within the same discipline.

It is aimed at research programs that, by their complexity and interdisciplinary nature, require a cross-disciplinary team approach to achieve significant progress and sustainability, thereby creating a culture for teaching and research that transcends traditional disciplinary boundaries. Clinical research or a clinical trial (phase I, I/II, or II) may be included as part of the proposed program.

Investigators are expected to work together to develop the research plan, determine the management structure, and prepare the application. It should be clear that all investigators have a substantial level of intellectual input into the proposed program. Collectively, the members of the teams should represent the appropriate diversity of expertise necessary for addressing the research question. Effort is expected to be appropriately balanced among the investigators and their respective teams.

Applicants must present a clear plan for how they would manage and facilitate meaningful collaboration among the separate research teams to enable successful completion of the proposed research. Participating institutions must be willing to resolve potential intellectual and material property issues/conflicts and subcontracting issues and remove institutional barriers to achieving high levels of cooperation.

This funding mechanism offers an attractive opportunity for investigators to test new ideas, explore new areas, and/or implement new approaches. These types of applicant responses are desired and encouraged. However, CPRIT staff and external scientific review committees have noted a significant amount of overlap of investigators (ie, some investigators proposing to lead or participate in several new activities), thereby making it difficult to discern where the investigators' interests truly lie. In addition, some investigators have submitted very ambitious applications requesting large sums of money but with minimal evidence of commitment to the project in terms of percentage effort. This RFA attempts to curb these practices while still avoiding excessively rigid rules that might stifle innovation; therefore, applications with deviations from guidelines stated in the RFA will be examined closely. Evidence of lack of commitment or excessive fragmentation will be a significant negative factor in funding decisions.

3. RESEARCH OBJECTIVES

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This RFA solicits applications for integrated programs of collaborative and cross-disciplinary research among multiple investigators and will focus on critical research areas that will contribute meaningfully to advancing knowledge of the causes, prevention, and/or treatment of cancer. CPRIT encourages applicants who seek to develop or apply state-of-the-art technologies, tools, and/or resources for cancer research, including those with projects having potential commercialization opportunities. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and survivorship. To fulfill this vision, applications may address any research topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or quality of life.

Because Multi-Investigator Research Awards, by definition, support collaborative research projects, this award mechanism will accommodate applications that encompass a wide variety of activities and administrative structures. Applicants may propose collaborative programs that are modest in size or those that are larger and more complex. CPRIT encourages cancer investigators from Texas to bring their best ideas forward for consideration. Creative, collaborative projects that address critical questions should leverage cancer research taking place in Texas into a leadership position from both national and international perspectives. Federal programs should not be duplicated; rather, when possible, their impact in the state of Texas should be enhanced.

4. FUNDING INFORMATION

This funding mechanism is intended to accommodate a wide variety of applications and organizational structures. Applicants may request a maximum of \$7,500,000 in total costs for a maximum period of 5 years. Exceptions to the maximum amount may be requested if extremely well justified. Funds may be used for salary and fringe benefits, research supplies, equipment, clinical costs, and travel to scientific/technical meetings or collaborating institutions. 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.

In an attempt to reduce the administrative difficulties in submitting programmatic and financial reports, Multi-Investigator Research Awards will be submitted as a single application. The PI will lead the project through the Administrative Core, which will be housed at the applicant institution. Individual projects and cores must be handled through subcontracts if participating institutions are located outside of the applicant institution. The applicant institution will develop the overall program budget with the assistance of individual participating institutions. Therefore, the institution that leads the Administrative Core will be responsible for coordinating subcontracts, submission of progress reports, and all related annual and financial reports. There will not be a requirement for other participating institutions to submit these reports to CPRIT.

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 Program.
- The Principal Investigator (PI) and Co-Principal Investigators (Co-PIs) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent. Individuals serving as a PI or Co-PI must reside in Texas during the time the research that is the subject of the grant is conducted. A major criterion for successful applications will be the level of expertise of the collaborative team that has been assembled. CPRIT encourages the creation of teams composed of researchers from Texas who have stellar reputations in their given areas of expertise. If necessary, applicants must eschew

institutional and regional considerations to assemble the best qualified of the state's investigators on a given subject into a superb collaborative team. Competing applications in a single area may fragment and dilute the best talent available. While CPRIT recognizes the value of competition, assembly of researchers with the best expertise for large-scale programs is encouraged to facilitate the highest level of cancer research throughout the state. CPRIT also encourages the inclusion of investigators from multiple institutions to facilitate interinstitutional collaboration.

- An individual serving as a PI may submit only 1 application under this RFA. An individual may serve as a Co-PI in more than 1 application but should ensure that he or she could dedicate adequate time and effort should more than 1 application be funded.
- 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. Collaborators should have specific and well-defined roles. 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. In no event shall equipment purchased under this award leave the state of Texas.
- 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 because of scientific misconduct or fraud 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 12](#) and [section 13](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

Resubmissions are available under this RFA. A MIRA application that was unfunded after a single review should be submitted as a resubmission under this RFA. Applicants are advised to address all noted concerns in the summary statements that were prepared for the original application review. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All previously unfunded MIRA submissions should be carefully reconstructed and take reviewers comments under consideration when resubmitting an application.

7. RENEWAL POLICY

Renewals are not available under this RFA. A project that was previously funded under the MIRA and would be a continuation of MIRA program activities must be submitted as a new application under this RFA. In preparing the new application, applicants should describe and demonstrate that appropriate/adequate progress has been made on the previously funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be incorporated into the application as well as patents and efforts at product development where appropriate.

8. CHARACTERISTICS OF MULTI-INVESTIGATOR RESEARCH AWARDS

8.1. Synergy

Successful multi-investigator research programs are characterized by an exceptionally synergistic theme. Applications in response to this RFA must bring together a strong group of research projects and necessary core resources that contribute to a common goal in cancer

research as a single, coherent entity. The overall program must provide greater value than the sum of its individual components.

Synergy between projects and cores to support the overall objective of the proposed program and the multidisciplinary focus of each project and core are essential aspects of the award mechanism and are major considerations of the review process.

It is envisioned that these research programs, once established, will interact extensively with each other and, if possible, with newly formed or established companies interested in bringing specific, Texas-based cancer discoveries to the market for the benefit of patients with cancer everywhere. To the extent possible, plans for such interactions should be developed and described.

8.2. Leadership

8.2.1. Principal Investigator (PI)

The overall research program will be directed and overseen by a PI. The PI is responsible for developing and managing an integrated and collaborative research environment that permits uninterrupted progress of the research projects regardless of distinct geographic locations of collaborators within the state. The PI must direct the required administrative core (see [section 8.4](#) and [section 9.2.10](#)). The PI is responsible for the submission of the application, all reporting requirements, and all budgeting decisions.

8.2.2. Co-Principal Investigator (Co-PI)

Each research project and core resource within the overall research program must be directed by a single individual designated as a Co-PI on the application for the overall research program. The Co-PI will be responsible for the research activities of his or her research project(s) and/or core resource(s) within the framework and goals of the overall research program. The PI may also direct a research project and/or core resource. Projects and cores located outside of the PI's institution must be supported through a subcontract with the applicant institution.

8.3. Research Projects

Research projects (also referred to as *projects* in this RFA) will challenge existing paradigms; develop or employ novel concepts, approaches, methodologies, tools, or technologies for the proposed cancer research area; or address important underexplored or unexplored areas. CPRIT

seeks to support original and innovative projects. The thrust of the Multi-Investigator Research Awards mechanism is to support research projects that 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.

Each project must be poised individually to make significant contributions to the field of cancer research as well as be complementary to the overall research program. Application of a single approach to multiple forms of cancer does not justify a request for multiple research projects.

The guidelines for research projects are as follows:

- Minimum: 3 projects
- Maximum: 5 projects
- Each research project must be directed by the PI or by a Co-PI. The PI or a Co-PI can direct only 1 project within the Multi-Investigator Research Award application.

8.4. Core Resources

Supporting core resources (also referred to as *cores* in this RFA) constitute integral components of multi-investigator research programs by providing the expertise and/or infrastructure essential to the completion of the individual research projects. Examples of core resources include, but are not limited to, administrative core, tissue/specimen core, sequencing/bioinformatics core, histopathology core, and imaging core. All applications submitted in response to this RFA must include an administrative core that comprehensively coordinates all activities proposed within the objectives of the projects and cores and is directed by the PI.

The guidelines for core resources are as follows:

- Minimum: Administrative core
- Maximum: 3 technical cores
- A maximum of 4 cores is permitted (ie, the administrative core and 3 technical cores).
- Each core must be directed by the PI or by a Co-PI. A Co-PI can direct 1 project and/or 1 technical core. The PI can direct 1 project and/or technical core in addition to the administrative core. The administrative core must be directed by the PI.
- Cores should include clear descriptions of the projects they are designed to support.
- Projects and cores are subject to different review criteria (see [section 10.4](#)). Research projects must **not** be submitted as cores in an attempt to circumvent the limitation on the

number of research projects that may be submitted as part of a single Multi-Investigator Research Award application.

8.5. Selection of Research Projects and Core Resources

The PI is expected not only to coordinate and develop the overall research program but also to *limit the number of projects and cores* to only those that are considered highly meritorious and significant within the context of the entire application. The collaborative impact, merit, and feasibility of all the projects—not the cores—will determine whether an application for a Multi-Investigator Research Award receives support. Investigators are strongly discouraged from including weaker projects in an effort to obtain a higher level of funding. Rather, inclusion of fewer, highly focused projects is strongly recommended.

8.6. Commitment of Time and Effort

Investigators are expected to commit *significant percentage effort* to research projects and cores. Although no minimum time commitment is required for the PI, a total commitment of 20% effort is desirable. Less than that can be viewed by reviewers as a lack of commitment to the program. Research project and core resource leads should commit at least 10% effort for each project and/or core that he or she directs.

Note: CPRIT requires that the percentage effort of the PI and/or Co-PI(s) remain the same in every year of support requested unless there is a corresponding change in the budget and level of activity of the project/core directed by the PI or the Co-PI(s) in question.

CPRIT recognizes that multi-investigator programs will vary significantly in size and scope; thus, a single guideline for commitment of time and effort is not appropriate for all applications. Applications should exhibit a reasonable correlation between time commitment and funds requested unless there are special circumstances, which must be explained. In addition, it should be clear from the other support information provided that the investigator will be able to achieve the required percentage effort and what activities may have to be contracted or curtailed to achieve the required percentage effort for the application submitted.

8.7. Participation on More than 1 Application

CPRIT is concerned that many investigators appear frequently as part of several different research programs, which makes it difficult to discern the investigators' commitment to a given project. CPRIT believes that this leads to weaker, less competitive applications. Therefore, CPRIT urges investigators to be named on only 1 Multi-Investigator Research Award application in a given funding cycle, regardless of their role. However, CPRIT recognizes that specific individuals directing and/or participating in core resources (e.g., biostatistics, bioinformatics, or histopathology cores) may be involved in multiple research studies.

A common set of tools may be applied in more than 1 situation, leading to economies of scale (but **not** duplications of budgets). Thus, exceptions to investigators being listed on only 1 application may be made if compelling justification for such exceptions and assurance of commitment (usually in the form of percentage effort) are provided. Reductions in percentage effort will usually not be approved after an application is funded unless there have been major changes in scope and, therefore, in budget.

9. RESPONDING TO THIS RFA

9.1. 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 August 11, 2015, and must be submitted by 3:00 PM central time on October 13, 2015. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

9.1.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications 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. 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.

9.2. 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.

9.2.1. Abstract and Significance (15,000 characters)

Clearly explain the question or problem to be addressed by the proposed overall research program and the approach to its answer or solution. Address how the proposed research, if successful, will have a major impact on the field of cancer research or on the care of patients with cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. State the synergistic value that the individual research projects and core resources present to the goals of the overall application. Summarize the proposed core resources. Clearly state the project(s) that the core resources will support and the synergistic value they provide to the goals of the research project(s).

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).

9.2.2. Layperson's Summary (10,000 characters)

Provide a layperson's summary of the proposed program. Describe, in simple, nontechnical terms, the overall goals of the proposed program, 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 10.1](#)) in evaluating the significance and impact of the proposed work.

9.2.3. Goals and Objectives (Maximum of 3 Goals and 3 Objectives per Goal for Each Project and Core)

Provide a list of 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. Goals and objectives should be listed for the overall project as well as for each project and core separately. Projects and cores should be labeled numerically (AC for the Administrative Core, Project 1 to Project 5, and Core 1 to Core 3) and be clearly identified. Goals and objectives for cores should indicate the project(s) to be supported.

Goals and objectives for the overall project should be listed under Administrative Core and prepared by the PI.

9.2.4. Timeline (Maximum of 1 Page per Project and Core)

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. Timelines should be listed for the overall program as well as for each project and core separately. Projects and cores should be labeled numerically (AC for the Administrative Core, Project 1 to Project 5, and Core 1 to Core 3) and be clearly identified. The timeline for the overall project should be listed under Administrative Core and prepared by the PI.

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.

9.2.5. Resubmission Summary (10 pages)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention.

All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

9.2.6. Overview of Overall Program (10 Pages)

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

Research Strategy: Describe the objectives of the research program and briefly summarize each component project and core resource.

Synergy: Describe how individual component projects provide synergistic value to the research program.

9.2.7. Research Project Abstract (Maximum of 5,000 characters per Project)

Clearly explain the question or problem to be addressed by the proposed project and the approach to its answer or solution. Address how the proposed research, if successful, will have a major impact on the field of cancer research or on the care of patients with cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. State the synergistic value that the project has to the overall research program and other projects and core resources in accomplishing the goals and objectives of the overall program.

9.2.8. Research Project Plan (Up to 25 Pages for Each Project)

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

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.

Synergy: Describe how the project provides synergistic value to the entire research program.

Biographical Sketches: A biographical sketch must be provided for each individual leading a project. Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 5 pages. The NIH Biosketch format is appropriate.

Vertebrate Animals and/or Human Subjects: If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for IRB approval or exemption and recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

Publications/References: Provide a concise and relevant list of publications/references cited for the research project.

Budget and Justification: While there will be one budget for the entire program, an individual budget and budget justification must be included for each project. A five year budget table with a justification of budget expenses should be sufficient. This budget should not be as detailed as the overall program budget, but rather a high level budget that allows reviewers to evaluate project expenses.

9.2.9. Core Resource Abstract (Maximum of 5,000 characters per Core Resource)

Clearly explain the question or problem to be addressed by the proposed core resource and the approach to its answer or solution. Address how the core will have a major impact on the field of cancer research or on the care of patients with cancer. Summarize how the proposed core resource creates new paradigms or challenges existing ones. State the synergistic value that the core resource has to the overall research program and other projects and core resources in accomplishing the goals and objectives of the overall program.

9.2.10. Core Resource Plan (Up to 25 Pages for Each Core Resource)

Background: Present the rationale behind the proposed core resource.

Support Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data demonstrating the capabilities of the core are encouraged but not required.

Synergy: Describe how the core resource provides synergistic value to the research program.

Biographical Sketches: A biographical sketch must be provided for each individual leading a core resource. Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 5 pages. The NIH Biosketch format is appropriate.

Vertebrate Animals and/or Human Subjects: If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for IRB approval or exemption and recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

Publications/References: Provide a concise and relevant list of publications/references cited for the core resource.

Budget and Justification: While there will be one budget for the entire program, an individual budget and budget justification must be included for each core. A five year budget table with a justification of budget expenses should be sufficient. This budget should not be as detailed as the overall program budget, but rather a high level budget that allows reviewers to evaluate core expenses.

9.2.11. Administrative Core Plan (5 Pages)

Describe the organizational and management structure that will be established to efficiently, effectively, and comprehensively manage all aspects of the research program. State how the leaders of individual projects and cores (i.e., the PI and the Co-PIs) will communicate and discuss results, report progress, and resolve potential problems throughout the duration of the research program.

9.2.12. Synergy Illustration (3 Pages)

Provide a detailed narrative and diagrammatic representation of interactions between the Administrative Core, all research projects, and all core resources of the proposed research program.

9.2.13. Vertebrate Animals and/or Human Subjects (5 Pages)

If vertebrate animals or human subjects or human biological samples will be used, please use this section to provide any additional details that may have not been covered in Research Project or

Core Resource Plans. If no additional space is needed to provide other information, applicants should mark this section as "Not Applicable". There is no need to duplicate information that is included in Sections 9.2.8 or 9.2.10.

9.2.14. Publications/References

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

9.2.15. 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. 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. Reasonable budgets clearly work in favor of the applicant.

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. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

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

- One budget will be submitted on behalf of the entire program and will include costs for individual projects and cores. While there will be 1 budget for the entire program, individual budget breakdowns must be included for each project and core resource as a part of the research or core resources plan. For programs that have outside institutions participating, a subcontract must be executed for that institution to receive CPRIT funds.
- 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 annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2016 is \$200,000; CPRIT FY 2016 is from September 1, 2015, through August 31, 2016.

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.

9.2.16. Biographical Sketches for Key Personnel (5 Pages Each)

Up to 5 additional biographical sketches for key personnel may be provided. Each individual biographical sketch must not exceed 5 pages. The NIH Biosketch format is appropriate. Biographical Sketches for Project and Core Co-PIs must be submitted as part of the Research Project or Core Resource plans.

9.2.17. 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 Co-PIs must be provided.

9.2.18. Institutional/Collaborator Support and/or Other Certification (15 Pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 15 pages may be provided.

9.2.19. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

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.

10. APPLICATION REVIEW

10.1. 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 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.

10.2. 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 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.

10.3. 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.

10.4. 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 project and core individually according to the primary criteria 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.**

10.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work in each project and core as well as the overall program as described 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: What is the innovative potential of the program? Does the program propose new paradigms or challenge existing ones? Does the program develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Investigators and biomedical personnel must want and need to know the results of CPRIT-funded research because such knowledge will change the ways in which they conduct their own research or approach and care for their patients. Programs that modestly extend current lines of research will not be considered for this award.

Research Plan for Research Projects: 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? Does the proposed project provide strong synergistic activities as part of a multidisciplinary collaboration? See [section 8.1](#).

Project Leader for Research Projects: Does the project leader demonstrate the required creativity, expertise, experience, and accomplishments to achieve the goals of the research project? Has the project leader devoted a sufficient amount of his or her time (percentage effort) to this project?

Synergy and Collaborative Teams: Does the proposed project provide strong synergistic activities as part of a multidisciplinary collaboration? That is, is the value of this program significantly greater than the sum of its parts? If core facilities are described, are they necessary and sufficient to support the project in achieving the overall goals proposed? Has the project assembled the best qualified collaborative and multidisciplinary teams to achieve the proposed goals? Are the levels of effort of the key personnel appropriate as outlined in [section 8.6](#)?

Relevance of Research Projects: Does the proposed research have a high degree of relevance to reduce the burden of cancer? This will be an important criterion for evaluation of projects for CPRIT support.

Sufficiency and Capability of Core Resources: Is the proposed core resource necessary? Does it have the needed facilities and sufficient resources to support the proposed research project(s) in accomplishing the proposed goals? Does it provide strong synergistic activities as part of a multidisciplinary collaboration? Is there a mechanism for prioritizing the work of the core?

Core Resources Leader: Does the core leader demonstrate the required expertise and experience to direct the core resource in supporting the research project(s)? Has the core leader devoted a sufficient amount of his or her time (percentage effort) to this resource?

Administrative Core Plan: Is the proposed organizational and management structure capable of comprehensively overseeing and coordinating all aspects and activities of the proposed research program?

Administrative Core Leader: Does the core leader demonstrate the required expertise and experience to direct the research program? Has the core leader devoted a sufficient amount of his or her time (percentage effort) to this activity? Are there plans for coordination of the program and for facilitating interactions among the program components?

10.4.2. 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?

11. KEY DATES

RFA

RFA release July 6, 2015

Application

Online application opens August 11, 2015, 7 AM central time

Application due October 13, 2015, 3:00 PM central time

Application review November 2015 to March 2016

Award

Award notification May 2016

Anticipated start date June 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