



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS

## RFA R-16-HIHR-2

### High-Impact/High-Risk Research Awards

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

Applications for this award mechanism are subject to institutional limits.

Applicants are advised to consult with their institution’s Office of Research and Sponsored Programs (or equivalent).

**Application Receipt Opening Date:** August 11, 2015

**Application Receipt Closing Date:** October 13, 2015

**FY 2016**

Fiscal Year Award Period

September 1, 2015–August 31, 2016

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## **RFA VERSION HISTORY**

Rev 07/06/15 RFA release

ARCHIVE

## **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**

CPRIT High-Impact/High-Risk (HIHR) Research Awards seek to provide short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new

insights into the etiology, diagnosis, treatment, or prevention of cancers. Because HIHR Research Awards are designed to support new ideas, preliminary data are not required. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. The HIHR Research Awards are expected to provide the foundation for individual or multiple investigator awards upon completion. Applicants must explain why more conventional sources of support are not available for the proposed research and how short-term funding will lead to strong applications for additional support.

Applications that might be described as “mini-R01s” will not be competitive. **The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data. There should be reasons for the idea to be plausible, but CPRIT acknowledges that most of the selected projects will ultimately fail to meet their primary goals. The rare proposals that succeed will be of sufficient importance to justify this program.** Applications may address any research topic related to cancer biology, causation, prevention, detection, screening, treatment, or survivorship.

### 3. RESEARCH OBJECTIVES

Areas of interest include laboratory research, translational studies, and population-based and/or clinical investigations. In that cancers arise from a large number of derangements of basic molecular and cellular functions, which, in turn, cause many alterations in basic biological processes, almost any aspect of biology may be relevant to cancer research, more or less directly. The *degree of relevance* to cancer research will be an important criterion for evaluation of projects for funding by CPRIT ([section 8.3.1](#)). For example, are alterations in the process in question *primarily* responsible for oncogenesis or secondary manifestations of malignant transformation? Will understanding the process or interfering with it offer selective and useful insight into prevention, diagnosis, or treatment of cancer? *Successful applicants for funding from CPRIT will have addressed these questions satisfactorily.*

### 4. FUNDING INFORMATION

Applicants may request a total of \$200,000 for a period of up to 24 months (2 years), inclusive of both direct and indirect costs. Because of the nature of this funding mechanism, renewal applications will not be accepted. Follow-on applications will not be funded until the time

requested for the HHR Research Award has passed. Award funds may be used to pay for salary and benefits, research supplies, equipment, and clinical costs. Requests for funds for travel to scientific meetings are not appropriate for this funding mechanism, nor are requests for funds to support construction and/or renovation. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

## 5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is also eligible for funding under this award mechanism.
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent and reside in Texas for the period of the time that the research that is the subject of the grant is conducted.
- A PI may submit only 1 new or resubmission application under this RFA during this funding cycle.
- One Co-PI may be included. 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.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.

- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [section 10](#) and [section 11](#). All statutory provisions and relevant administrative rules can be found at [www.cprit.state.tx.us](http://www.cprit.state.tx.us).

## **6. RESUBMISSION POLICY**

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. This policy is in effect for all applications submitted to date. See [section 7.2.5](#).

## **7. RESPONDING TO THIS RFA**

### **7.1. 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 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.

Applications will be accepted beginning at 7 AM central time on August 11, 2015, and must be submitted by 3 PM central time on October 13, 2015. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

### **7.1.1. 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 grant 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.

## **7.2. 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 that do not meet the eligibility requirements listed in [section 5](#) will be administratively withdrawn without review.

### **7.2.1. Abstract and Significance (5,000 characters)**

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

### **7.2.2. 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 prevention research,



early diagnosis, 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 8.1](#)) in evaluating the significance and impact of the proposed work.

### **7.2.3. 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.

### **7.2.4. Timeline (1 page)**

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

### **7.2.5. Resubmission Summary (1 page)**

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. Applicants may prepare a fresh Research Plan or modify the original Research Plan and mark the changes. However, 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.

### 7.2.6. Research Plan (4 pages)

**Background:** Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed. Preliminary data are not required, but strong reasoning and literature support will obviously enhance the application.

**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.

### 7.2.7. Vertebrate Animals and/or Human Subjects (1 page)

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 recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

### 7.2.8. Publications/References

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

### 7.2.9. 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. Applications requesting more than \$200,000 (total costs) over a maximum period of 24 months (2 years) will be administratively withdrawn.

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

- Major equipment purchases are discouraged for this funding mechanism. 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.cpr.it.state.tx.us](http://www.cpr.it.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; etc) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

#### **7.2.10. Biographical Sketches (2 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 2 pages.

#### **7.2.11. 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.

#### **7.2.12. Institutional/Collaborator Support and/or Other Certification (2 pages)**

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 2 pages may be provided.

#### **7.2.13. 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.**

## **7.2.14. Institutional Limits**

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

The limit on the number of applications may seem restrictive, but experience indicates that truly innovative ideas that are appropriate for this award mechanism are uncommon. CPRIT expects institutions to initiate an internal review process and only authorize submission of the appropriate number of applications that have been rigorously judged to be responsive to this RFA. Institutional limits (which need not be fully used) are as follows: University of Texas M. D. Anderson Cancer Center, 10; Baylor College of Medicine, 10; University of Texas Southwestern Medical Center, 10; University of Texas Health Science Center at San Antonio, 10; University of Texas Health Science Center at Houston, 10; University of Texas at Austin, 10; University of Texas Medical Branch, 10; Texas A&M University, 10; Texas A&M University Health Science Center, 10; Texas Tech University, 10; Texas Tech University Health Sciences Center, 5; Texas Tech University Health Sciences Center at El Paso, 5; all others academic research institutions, 5 each; public or private companies, 1 each.

## **8. APPLICATION REVIEW**

### **8.1. Review Process Overview**

All eligible applications will be evaluated using a 2-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. 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 the 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.

## **8.2. 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 when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

### 8.3. Review Criteria

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.**

#### 8.3.1. 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:** Is the application clearly responsive to the RFA and specifically to the HIHR Research Award mechanism? What is the innovative potential of the project? 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? Responsive applications will be highly speculative or exploratory; they need not be based on preliminary data but must have the potential for high scientific payoff because of exceptionally promising ideas.

**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 a sound 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, expertise, experience, and accomplishments 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 (percentage effort) to this project?

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

### 8.3.2. Secondary Criteria

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

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

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

**Budget and Duration:** Are the budget and the duration appropriate for the proposed work?

## 9. 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 PM central time  
Application review November 2015 to March 2016

### Award

Award notification May 2016  
Anticipated start date June 2016



## 10. 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](http://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](http://www.cprit.state.tx.us).



## 11. 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 the demonstration of available funding.

## 12. CONTACT INFORMATION

### 12.1. 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](mailto:Help@CPRITGrants.org)

### 12.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

**Email:** [Help@CPRITGrants.org](mailto:Help@CPRITGrants.org)

**Website:** [www.cprit.state.tx.us](http://www.cprit.state.tx.us)