



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

**REQUEST FOR
APPLICATIONS**

RFA R-13-HIHR-1

**High-Impact/High-Risk
Research Awards**

FY 2013

Fiscal Year Award Period
September 1, 2012–August 31, 2013

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).

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RFA VERSION HISTORY

- Rev 2/16/12 RFA release
- Rev 3/8/12 Announcement box revised (p.4)
- Prevention Research applications may be submitted under any Research award mechanism RFA

ARCHIVE

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT); CPRIT may issue \$3 billion in general obligation bonds over 10 years to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and 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 this State; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT believes that the best ideas come from Texas-based researchers, rather than from CPRIT staff. To that end, CPRIT strives to keep RFAs simple and as free from rules and restrictions as possible. **This RFA may and should be used for any kind of research**—basic, translational, clinical, or prevention. CPRIT reviewers are established and accomplished scientists who are encouraged to support excellence and weigh risk against potential gain. CPRIT review committees are constituted broadly. There are no quotas for types or areas of research. Simply stated: CPRIT tries to fund the projects that can make the biggest difference.

2. EXECUTIVE SUMMARY

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This Request for Applications (RFA) solicits applications for relatively short-term, high-impact/high-risk projects that are especially innovative in nature, exploring new concepts or new avenues of cancer research. CPRIT encourages applications that seek to apply or develop state-of-the-art technologies, tools, and/or resources for cancer research, including those with 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 cure. To fulfill this vision, applications may address any research topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure.

3. MECHANISM OF SUPPORT

CPRIT High-Impact/High-Risk 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 High-Impact/High-Risk 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 High-Impact/High-Risk 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.**

4. RESEARCH OBJECTIVES

Areas of interest include laboratory research, translational studies, and/or clinical investigations. In that cancers arise from a large number of derangements of basic molecular and cellular functions and 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. 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.*

5. 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 High-Impact/High-Risk 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 percent of the total award amount.

6. KEY DATES

RFA

RFA release February 16, 2012

Application

Online application opens April 12, 2012, 7 a.m. Central Time

Application due May 31, 2012, 3 p.m. Central Time

Application review September/October 2012

Award

Award notification November 2012

Anticipated start date December 1, 2012

7. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism.
- A public or private company is also eligible for funding under this award mechanism.
- The Principal Investigator (PI) must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may submit only one new or resubmission application under this RFA during this funding cycle.
- One Co-PI may be included. Collaborators should have specific and well-defined roles.

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- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
 - A PI may resubmit an application that was previously not funded (see Sections 8 and 10.4.6).
 - 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 Sections 11 and 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

8. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once. More than one resubmission is not permitted. This policy is in effect for all applications submitted to date. See Section 10.4.6.

9. APPLICATION REVIEW

9.1. Outline

All eligible applications will be reviewed using a two-stage process: (1) Peer review, and (2) programmatic review. In the first stage, applications will be evaluated by an independent scientific merit review committee using the criteria listed below. In the second stage, applications judged to be most meritorious by review committees will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the merit review committees and programmatic priorities.

9.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all council and committee members are required to sign nondisclosure statements regarding the contents of the applications. All council and committee members will be non-Texas residents and operate under strict conflict of interest prohibitions. Under no circumstances should institutional personnel

and/or individual applicants initiate contact with any member involved in the peer review process (with the exception of members of the CPRIT Scientific Review Office), the CPRIT executive director, or any member of the CPRIT Oversight Committee regarding the status or substance of the application. Violations of this prohibition will result in the administrative withdrawal of the application. Any communication regarding the application should be directed to the CPRIT Research HelpDesk and/or CPRIT's Scientific Review Office.

9.2. 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.**

9.2.1. Primary Criteria

Primary criteria will evaluate the scientific merit 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.

Responsiveness to RFA (especially High Impact): Is the application clearly responsive to the RFA and specifically to the High-Impact/High-Risk 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 under- 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 reasonable scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant demonstrate the required creativity, expertise, experience, and accomplishments to make a significant contribution to cancer 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?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This will be an important criterion for evaluation of projects for CPRIT support (see Section 4).

9.2.2. 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.

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: Is the stated budget and duration appropriate for the proposed work?

10. SUBMISSION GUIDELINES

10.1. Institutional Limit

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 High-Impact/High-Risk 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 as soon as possible and only authorize submission of the appropriate number of applications that have been judged rigorously 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, 5; University of Texas Health Science Center at Houston, 5; University of Texas at Austin, 5; University of Texas Medical Branch, 5; Texas A&M University, 5; Texas A&M University Health Science Center, 5; Texas Tech University, 5; Texas Tech University Health Sciences Center (combined campuses), 5; all others, 2 each.

10.2. Online Application Receipt System

Applications will be accepted beginning at 7 a.m. Central Time on April 12, 2012 and must be submitted via the CPRIT Application Receipt System (<https://CPRITGrants.org>). **Only applications submitted at this portal will be considered eligible for evaluation.** 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 on the application. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

10.3. Submission Deadline

All applications must be submitted by 3 p.m. Central Time on May 31, 2012.

10.4. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Submissions that are missing one or more components or do not meet the eligibility requirements listed in Section 7 will be administratively withdrawn without review.

10.4.1. Application Signing Official (ASO)

The ASO is an individual authorized to submit an application on behalf of an organization. An ASO must be identified and assigned to the application by the PI. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. The ASO must also create a user account in the online application receipt system.

10.4.2. Grants Contract/Office of Sponsored Projects Official

The grants contract/Office of Sponsored Projects official is the individual who will manage the grant if an award is made. This individual must be identified and assigned to the application either by the PI or by the ASO. The grants contract/Office of Sponsored Projects official must also create an ASO-type user account in the online application receipt system.

10.4.3. 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.

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

Provide a layperson's summary of the proposed work. Describe, in very simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research. 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.

10.4.5. Overall Goals and Timeline (1 page)

Outline the specific aims of the research project. 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.

10.4.6. 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.

10.4.7. Research Plan (4 pages)

Background: Briefly 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.

Specific Aims: Concisely state the specific aims that will be pursued.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches.

Mechanism of Support: Explain briefly why this mechanism is appropriate. Why is this application not suitable for more conventional funding? At what stage will this project become competitive for conventional support?

10.4.8. 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.

10.4.9. Publications/References

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

10.4.10. 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 from consideration.

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 percent of the total award amount (5.263 percent 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 (e.g., 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.

10.4.11. 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 two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

10.4.12. Current and Pending Support

State the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a two-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.

10.4.13. 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.

10.4.14. 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 one or more of these components, exceed the specified page, word, or budget limits, or do not meet the eligibility requirements listed above will be administratively rejected without review.

11. AWARD ADMINISTRATION

Texas law requires that CPRIT research awards be made by contract between the applicant and CPRIT. Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, and terms relating to intellectual property rights. These contract provisions are specified in CPRIT's administrative rules, which are available at www.cprit.state.tx.us.

All CPRIT awards will be made to institutions, not to individuals. Applicants who change their institutional affiliation during the time period of the award must submit a written request to CPRIT to transfer the award to the new institution. Transfer of awards to institutions outside of Texas is not permitted.

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 receipt of these reports. Forms and instructions will be made available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires the CPRIT award recipient to 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, 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 e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: February 16,, 2012, to May 31, 2012, (excluding public holidays)

Hours of operation: Monday through Friday, 7 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: ResearchHelp@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 Scientific Review Office.

Tel: 512-305-8491

E-mail: ResearchHelp@CPRITGrants.org

Web site: www.cprit.state.tx.us