



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

**REQUEST FOR
APPLICATIONS**

RFA R-11-HIHR-1

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

2010–2011

Fiscal Year Award Period
September 1, 2010 — August 31, 2011

Applications for this award are subject to institutional caps. 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 3/1/10 RFA release
- Rev 3/5/10 Updated Section 9.2.2.5, Supplemental Documents
- Institutional/Collaborator Support and/or Other Certification: optional
 - Summary Statements: required for resubmission applications

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, 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.

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 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 up to \$200,000 over 24 months, 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 five percent of the total award amount.

6. KEY DATES

RFA

RFA release March 1, 2010

Application

Online application opens May 10, 2010, 7 a.m. Central Time

Application due June 10, 2010, 3 p.m. Central Time

Application review September/October 2010

Award

Award notification November 2010

Anticipated start date January 2011

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; public and private companies must use the “Company Investment” award mechanism (next likely submission deadline: October/November 2010).
- 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.
- 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 submit only one application under this RFA during this funding cycle. One Co-PI may be included. Collaborators should have specific and well-defined roles.
- A PI may resubmit an application that was previously not funded (see Section 9.2.2.4).
- 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 10 and 11. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

8. APPLICATION REVIEW

8.1. 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 panel using the criteria listed below. In the second stage, applications judged to be most meritorious by review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the merit review panels and programmatic priorities. Each stage of application review is conducted completely confidentially, and all panel members are required to sign nondisclosure statements regarding the contents of the applications. All panel 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 individual conducting peer review, 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.

8.2. 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.**

8.2.1. 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: 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?

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, above.

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?

8.2.2. 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 the approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Duration: Is the stated duration appropriate for the proposed work?

9. SUBMISSION GUIDELINES

9.1. 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 the 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 caps (which need not be fully used) are as follows: University of Texas M. D. Anderson Cancer Center, 14; Baylor College of Medicine, 10; University of Texas Southwestern Medical Center, 7; 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, 4; Texas A&M University, 3; Texas A&M University Health Science Center, 3; Texas Tech University, 3; Texas Tech University Health Sciences Center, 3; all others, 2 each.

9.2. Online Registration

Applications will be accepted beginning at 7 a.m. Central Time on May 10, 2010 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.** All applicants must register a user name to start and submit an application. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

9.2.1. Application Submission Deadline

All applications must be submitted by 3 p.m. Central Time on June 10, 2010.

9.2.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of the online application.

9.2.2.1. Contact Information

Enter all required applicant and Application Signing Official (ASO) information along with the application title.

9.2.2.2. 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. 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.

9.2.2.3. Layperson 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 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 Summary.

9.2.2.4. 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?

Human Studies: 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 mechanism.

Goals and Timeline: Provide an outline of the project goals, including anticipated major milestones tracked and the timeline proposed to accomplish the goals. This information will be made publicly available if the application is recommended for funding. Do not include any proprietary information in this section.

Resubmission: An application previously submitted to CPRIT but not funded may be resubmitted 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 reconstructed carefully; 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.

9.2.2.5. Supplemental Documents

References: Provide a concise and relevant list of references cited for the application.

Budget and Justification: Provide a justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, other expenses, and indirect costs. **Applications requesting more than \$200,000 (total costs) over a maximum of 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.

Biographical Sketches: 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. Up to two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

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 two-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application.

Institutional/Collaborator Support and/or Other Certification: 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.

Summary Statements (Resubmission): If the application is being resubmitted, applicants must provide the summary statement of the original application.

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.

10. 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.

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.

11. 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.

12. CONTACT INFORMATION

12.1. 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: March 1, 2010 to June 10, 2010 (excluding public holidays)

Hours of Operation: Monday through Friday, 8 a.m. to 5 p.m. Central Time

Tel: 866-941-7146

E-mail: ResearchHelp@CPRITGrants.org

12.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Scientific Review Office:

Tel: 512-305-8491

E-mail: ResearchHelp@CPRITGrants.org

Web: www.cprit.state.tx.us