



CANCER PREVENTION AND
CPRIT
RESEARCH INSTITUTE OF TEXAS

**REQUEST FOR
APPLICATIONS
RFA R-10-H1**

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

2009–2010

There is a cap on the number of High-Impact/High-Risk Research Award applications that may be submitted per institution. Applicants are advised to consult with their institution's Office of Research and Sponsored Programs (or equivalent).

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 innovative, developmental, or exploratory in nature targeting 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 proposals for additional support.

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 may not be funded until the time requested for the High-Impact/High-Risk Research Award has passed. Grant 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.

6. KEY DATES

RFA release	August 21, 2009
Online application opens	September 15, 2009, 7 a.m. Central Time
Application due	October 8, 2009, 3 p.m. Central Time
Application review	December 2009/January 2010
Award notification	January/February 2010
Anticipated start date	February/March 2010

7. ELIGIBILITY

- The applicant must be a Texas-based entity, including a public or private institution of higher education, academic health institution, university, government organization, nongovernmental organization, other public or private company, or an individual residing in Texas.
- The investigator 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.
- An investigator may submit only one application under this RFA during this funding cycle.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the applicant 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 member involved in the peer review process (with the exception of members of the CPRIT Scientific Review Office) regarding the status or substance of the application. Violations of this prohibition will result in the administrative withdrawal of the application.

8.2. 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 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 but will reflect the reviewers' overall impression of the application.

8.3. 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.

Relevance: The degree of relevance to cancer research will be an important criterion for evaluation of projects for CPRIT support. See Section 4, above.

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? Projects that extend current lines of research or transfer findings from one cancer type to another will not be considered for this award. Responsive applications will include those that are highly speculative or exploratory and that may not be based on preliminary data but 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 sufficient 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?

8.4. 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, have the appropriate guidelines relating to participation risk, inclusion, and protection been addressed?

Budget: Is the budget appropriate for the proposed work?

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. This number is based on the number of National Cancer Institute grants awarded to an institution (with arbitrary maxima and minima). Institutions should initiate an internal review process as soon as possible and only authorize submission of the appropriate number of applications. The maximum number of applications that may be submitted per institution are as follows: University of Texas M. D. Anderson Cancer Center, 20; Baylor College of Medicine, 11; University of Texas Southwestern Medical Center, 6; University of Texas Health Science Center at San Antonio, 4; University of Texas Medical Branch, 4; University of Texas at Austin, 3; all others, 2 each.

9.2. Online Registration

Applications will be accepted beginning at 7 a.m. Central Time on September 15, 2009, and must be submitted via the CPRIT Application Receipt System (www.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.

9.3. Application Submission Deadline

All applications must be submitted by 3 p.m. Central Time on October 8, 2009.

9.4. Application Components

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

9.4.1. Contact Information

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

9.4.2. Abstract (1,500 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution.

9.4.3. Significance (1,500 characters)

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.

9.4.4. 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 proposal 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 Institutional Review Board approval or exemption and for recruitment of subjects or acquisition of samples that will meet the time constraints of this mechanism.

Timeline: Provide an outline of anticipated major milestones tracked in the proposed project.

9.4.5. Supplemental Documents

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

Budget and Justification: Provide a brief outline and 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. 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. Applicants should be aware that Texas law limits the amount of indirect costs that may be funded by CPRIT grants. Guidance regarding indirect cost recovery can be found in the administrative rules proposed by CPRIT. The proposed rules and the statute can be found at www.cpritis.state.tx.us. Applications requesting more than \$200,000 (total costs) will be administratively withdrawn from consideration.

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. 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, duration, and title 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.

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 must 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 proposed administrative rules, which are available at www.cprit.state.tx.us. The proposed rule related to CPRIT contract provisions, as well as other proposed rules regarding the CPRIT grant process, are expected to become final by November 10, 2009. The public, including applicants, are invited to provide written comments to CPRIT on the proposed rules by September 28, 2009. Although CPRIT does not anticipate substantive changes to the final rules, to the extent that the final rules adopted by CPRIT materially change application requirements provided herein, applicants will be notified of any changes and provided an opportunity to revise the application to fully comply with the final rules.

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 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 cancer research grant recipient to demonstrate that it has an amount of funds equal to one-half of the grant dedicated to the research that is the subject of the grant. CPRIT has proposed an administrative rule regarding how a grant recipient may fulfill this requirement. The proposed rule is available at www.cprit.state.tx.us. The public, including potential applicants, are invited to provide written comments to CPRIT on the proposed rules by September 28, 2009. The rule is expected to be final by November 10, 2009.

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 the scientific aspects of applications.

Dates of Operation: September 15, 2009 to October 8, 2009

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