

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA R-11-IIRA-1

Individual Investigator Research Awards

2010-2011

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

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RFA VERSION HISTORY

Rev 3/1/10 RFA release

Rev 3/5/10 Updated Section 9.1.2.5, Supplemental Documents

- Institutional/Collaborator Support and/or Other Certification: optional
- Summary Statements: required for resubmission applications



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 innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. 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 will look with special favor on new approaches to be taken or new areas of investigation to be explored by established investigators and on supporting the research programs of the most promising investigators at the beginning of their research careers. Applicants need not be trained specifically in cancer research. Indeed, CPRIT strongly encourages investigators from other fields, including the mathematical, physical, chemical, and engineering sciences, to bring their expertise to bear on the exceptionally challenging problems posed by cancer. 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 topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure.

3. MECHANISM OF SUPPORT

The goal of awards made in response to this RFA is to fund exceptionally innovative research projects with great potential impact that are directed by a single investigator. This award allows experienced or early career—stage cancer researchers the opportunity to explore new methods and approaches for investigating a question of importance that has been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies. Access to a clinical environment and interaction with translational cancer physician-scientists are highly desirable.

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 maximum of \$500,000 in total costs per year for up to 3 years. Exceptions to the \$500,000 per year limit may be requested if extremely well justified (see Section 9.1.2.5). Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, clinical costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism.

State law limits the amount of award funding that may be spent on indirect costs to no more than 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—Texasbased organizations are not eligible to receive CPRIT funds.
- Because this award mechanism is intended to support research directed by a single investigator, only one Co-PI may be included. Collaborators should have specific and welldefined roles. This award mechanism should not be used for applications that are better suited for the Multi-Investigator Research Awards mechanism.
- A PI may submit only one application under this RFA during this funding cycle.

- A PI may resubmit an application that was previously not funded (see Section 9.1.2.4).
- 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

To ensure the timely review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications will be initially evaluated by CPRIT Scientific Research and Prevention Programs committee members for scientific merit and impact based on the introductory material presented in the application (see Section 9.1.2.2). Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. The applicant will be notified of a decision to disapprove (triage) the application at this stage when it is made.

Applicants are advised to prepare their introductory material wisely. Applicants should not waste this precious space by stating obvious facts (e.g., that cancer is a bad disease; that better diagnostic and therapeutic approaches are needed urgently; that the type of cancer of interest to the PI is important, vexing, or deadly; etc.). CPRIT is well aware of these facts.

Applications that meet the requirements of the initial evaluation 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.

Impact and Responsiveness to RFA: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer diagnosis or treatment for patients? Is the application innovative? 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 modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially that traditionally funded by other mechanisms, will not be competitive.

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 sufficient preliminary data and/or 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? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to this project?

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.

Budget: Is the budget appropriate for the proposed work?

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. 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.

9.1.1. Application Submission Deadline

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

9.1.2. Application Components

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

9.1.2.1. Contact Information

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

9.1.2.2. 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. Explain how this research plan represents a new direction for the PI. Proposals that represent logical extensions of ongoing work funded from other sources will not be competitive.

Note: It is the applicant's responsibility to capture CPRIT's attention with the Abstract and Significance statement alone. At this stage of initial evaluation, applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest will be excluded from further peer review. Because of the volume of applications to be reviewed, comments made by reviewers at this stage of initial evaluation will not be provided to applicants (also see Section 8.1, above).

9.1.2.3. 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.

9.1.2.4. Research Plan (10 pages)

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

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.

Goals and Timeline: Provide a brief statement of the project goals 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.

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.

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 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. Applicants preparing a resubmission may use up to half a page of the 10-page Research Plan to describe the approach to the resubmission.

9.1.2.5. Supplemental Documents

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

Budget and Justification: Provide a compelling, justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applicants are advised NOT to interpret the maximum allowable request under this award as an invitation to expand the budget to this level. Reasonable budgets clearly work in favor of the applicant. However, if there is a highly specific and defensible need to request more than \$500,000 in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

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

- 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.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2011 is \$200,000; CPRIT FY 2011 is from September 1, 2010 through August 31, 2011. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

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 4 pages may be provided.

Summary Statements (Resubmission): If the application is being resubmitted, applicants <u>must</u> 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