



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

**REQUEST FOR
APPLICATIONS**

RFA R-10-COMP1

Company Investment

2009–2010

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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 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, treatment, and potential 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 as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This RFA solicits applications for innovative **products** addressing critically important needs related to diagnosis, prevention, and/or treatment of cancer and the **product development infrastructure** needed to support these efforts. CPRIT encourages applications that seek to apply or develop state-of-the-art products, services (for example, contract research organization services), technologies, tools, and/or resources for cancer research, prevention, or treatment. 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 Company Investment awards made in response to this RFA is to finance the development of innovative products, services, and infrastructure with significant potential impact. These investments will allow companies or limited partnerships located in Texas, or those that are willing to relocate to Texas, the opportunity to further the development of new products for the diagnosis, treatment, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment or research gap. This investment award is intended to support companies undertaking product research and development in Texas with Texas-based employees. In determining eligibility for investment awards, CPRIT will evaluate whether applicants have a significant presence in Texas or are willing to relocate to Texas.

4. OBJECTIVES

The long-term objective of this award is to support commercially oriented translational research, therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA (with the exception of infrastructure applicants) should be the intent to develop products that would eventually be approved for marketing for the diagnosis, prevention, or treatment of cancer. Eligible products or services include, but are not limited to, therapeutics (e.g., small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of development include translational research, proof-of-concept studies, preclinical studies, and Phase I or Phase II clinical trials. By exception, Phase III clinical trials and later stage commercialization projects will be considered where circumstances warrant CPRIT investment.

5. FUNDING INFORMATION

No maximum will be set on the amount of funding that can be requested. Funding will be milestone driven. Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property protection, external consultants and service providers, and other appropriate development costs, subject to certain limitations set forth by Texas law. If a company is working on multiple projects, care should be taken to ensure

that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the State of Texas.

By law, all funds for multiyear awards must be set aside from the CPRIT budget of the first year in which the award is made. CPRIT has less than \$200 million to be spent on research programs during each of its first 2 years. Thus, a \$4 million per year award for 5 years would consume 10 percent of CPRIT's research budget in either of its first 2 years. Requests of that magnitude must be especially compelling. Some highly ambitious programs might start with more circumscribed goals with the expectation that additional funds could be awarded after benefits have been demonstrated.

6. RESPONDING TO THIS RFA

Letter of Intent: All applicants must submit a letter of intent indicating that they will be submitting an application in response to this RFA. Letters of intent will **not** be evaluated and will be used only to plan the workload of the review committees.

7. KEY DATES

RFA

RFA release November 20, 2009

Letter of Intent

Online receipt system opens December 1, 2009, 7 a.m. Central Time

Letter of intent due January 12, 2010, 3 p.m. Central Time

Application

Online application opens February 12, 2010, 7 a.m. Central Time

Application due March 1, 2010, 3 p.m. Central Time

Application review May 2010

Award

Award notification June 2010

Anticipated start date August 2010

8. ELIGIBILITY

- The applicant must be a Texas-based entity or an entity located in Texas at the time a contract for a Company Investment award is executed. This investment award is intended to support companies undertaking product research and development in Texas with Texas-based employees. In determining eligibility for investment awards, CPRIT will evaluate whether applicants have a significant presence in Texas or are willing to relocate to Texas.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. Subcontracting entities may include public, not-for-profit, and for-profit entities. Preference will be given to applicants with Texas-based subcontractors or collaborators. To the extent that Texas-based subcontractors or collaborators are not available, non-Texas-based collaborators and subcontractors may be used. However, non-Texas-based collaborators and subcontractors are not eligible to receive funds from CPRIT unless exceptional circumstances are demonstrated and approved by CPRIT.
- An entity 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 11 and 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

9. APPLICATION REVIEW

9.1. Outline

To ensure the timely review of only the most innovative and cutting-edge programs with the greatest potential for advancement of cancer diagnosis and treatment, all eligible applications will be initially evaluated for scientific and commercial merit and impact based on the introductory material presented in the application (see Sections 10.3.2.2 and 10.3.2.3).

Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review in this cycle. The applicant will be notified of such a decision when it is made.

Applications that meet the requirements of the initial evaluation will be reviewed using a three-stage process: (1) Scientific peer review, (2) intellectual property legal review, and (3) commercial assessment. 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. Under no circumstances should company personnel and/or individual applicants initiate contact with any member involved in the peer review process regarding the status or substance of the application. Violations of this prohibition will result in the administrative withdrawal of the application.

9.2. Review Criteria

Review of applications will be based on the following criteria:

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. See Section 4.

Responsiveness to RFA: Is the application clearly responsive to this RFA? What is the innovative potential of the product, service, or infrastructure proposed? Does the applicant propose new paradigms or challenge existing ones?

Commercial Potential: Is there demonstration of proof of relevance, and does the product fulfill a clear unmet medical or infrastructure need? Has work been conducted that supports the advancement of the proposed product, service or technology? Can the product be produced or manufactured in a commercially viable fashion? Is there appropriate basis for a reimbursement strategy? Is there an adequate market to support the investment? Is a strategy identified to appropriately differentiate a product or service from the competition?

Development Plan and/or Regulatory Path: Is the development plan and/or regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both a positive and a negative outcome? Does the budget appropriately support the plan?

Intellectual Property: Do exclusive rights to the intellectual property exist? Is there a clear understanding of the chain of ownership of the intellectual property? Is there freedom to operate? Have patent, copyright, or trademark applications been filed?

Budget: Is the budget appropriate for the proposed work? Does the amount requested enable the entity to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is it clear how funds will be used? Does the

proposed investment fund the development of the proposed product, service, or technology to a point where, if the results are positive, it is likely that the project will be able to attract further financial support outside of CPRIT?

Management: Does the applicant have the appropriate level of management experience to execute the stated strategy? Does the team have the needed experience or access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan? Are the levels of effort of the key personnel appropriate?

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

10. SUBMISSION GUIDELINES

10.1. Online Registration

All applicants must register a user name at the CPRIT Application Receipt System (<https://CPRITGrants.org>) to start and submit a letter of intent and an application. **Only letters of intent and applications submitted at this portal will be considered eligible for evaluation.**

10.2. Letter of Intent

Letters of intent will be accepted via the CPRIT Application Receipt System beginning at 7 a.m. Central Time on December 1, 2009. **All applicants must submit a letter of intent.** Applications submitted without prior submission of a letter of intent will not be accepted.

10.2.1. Letter of Intent Submission Deadline

All letters of intent must be submitted by 3 p.m. Central Time on January 12, 2010.

10.2.2. Letter of Intent Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of the letter of intent. Applicants will be required to submit the following information:

- (i) Application title
- (ii) Period of performance
- (iii) Approximate total award requested
- (iv) Principal Investigator name and institutional affiliation
- (v) Company investment letter of intent (use form template provided on the CPRIT Application Receipt System)

10.3. Application

Applications will be accepted via the CPRIT Application Receipt System beginning at 7 a.m. Central Time on February 12, 2010.

10.3.1. Application Submission Deadline

All applications must be submitted by 3 p.m. Central Time on March 1, 2010.

10.3.2. Application Components

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

10.3.2.1. Contact Information

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

10.3.2.2. Executive Summary (3 pages)

Clearly explain the product, service, technology, or infrastructure proposed; competition; market need and size; summary of development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.3.2.3. Significance Statement (1,500 characters)

Clearly address how the proposed project, if successful, will have a major impact on the care of patients with cancer.

Note: It is the applicant's responsibility to capture CPRIT's attention with the executive summary and significance statement alone. At this stage of initial evaluation, applications that are judged to offer only modest contributions to the field of cancer will be excluded from further peer review.

10.3.2.4. Business and Research Plan (25 pages)

The business plan should include background on the target disease; the diagnostic or infrastructure challenge; a description of the product, service, technology, or infrastructure;

assessment of the competition; market size; regulatory and reimbursement path; development and/or implementation plans; management; boards (including Scientific Advisory Boards); key personnel; and budgets. The research plan should state the specific aims to be tested or addressed by the research described in the application. Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data are encouraged. Provide an outline of anticipated major milestones tracked in the proposed project.

10.3.2.5. Supplemental Documents

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

Budget and Justification: Provide an 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. The budget must be aligned with proposed milestones. 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 proceeds to no more than 5 percent of the total award. Guidance regarding indirect cost recovery can be found in CPRIT's Policies and Procedures Guide. The guide, proposed rules, and the statute can be found at www.cprit.state.tx.us. The maximum annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2010 is \$200,000; CPRIT FY 2010 is from September 1, 2009 through August 31, 2010. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs.

Biographical Sketches: Applicants should provide a biographical sketch for each member of the senior management team that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. 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.

Applications that are missing one or more of these components, exceed the specified page or word 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. The contract will include mandatory reimbursement terms and conditions should the recipient relocate outside of the State during the term of the award contract or within 3 years after the final payment is made by CPRIT. Recipients should also be aware that the funding award contract will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. CPRIT will negotiate a mutually agreed-on financial interest with the recipient as well as other terms appropriate to the product, service, or infrastructure being developed. Investment grant funds may only be distributed on a reimbursement basis under Texas law.

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.

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 and commercialization aspects of applications.

Dates of Operation (preapplication): December 1, 2009 to January 12, 2010

Dates of Operation (application): February 12, 2010 to March 1, 2010

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

Tel: 866-941-7146

E-mail: ResearchHelp@CPRITGrants.org

13.2. Commercialization Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this funding opportunity, should be directed to the CPRIT Commercialization Review Office:

Tel: 512-305-8484

E-mail: ResearchHelp@CPRITGrants.org

Web: www.cprit.state.tx.us

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