CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-11-COMP-1

Company Commercialization Awards

2010-2011

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

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RFA VERSION HISTORY

Rev 7/23/10 RFA release

Rev 8/5/10 Revised Section 7, Eligibility
- Only one co-applicant is permitted on an application

Rev 8/5/10 Revised Section 9.1, Application Components
- Added Section 9.3.1, Commercialization Review Fee: required
- Added Section 9.3.3, Laypersons' Summary: required
- Added Section 9.3.4, Scope of Work and Milestones: required

Rev 8/5/10 Revised Section 9.3.9, Supplemental Documents
- Organizational/Collaborator Support and/or Other Certification: optional

Rev 8/20/10 Revised Section 6, Key Dates
- Clarified year for application review: November 2010-March 2011

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 possible 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 the State of Texas; 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 Request for Applications (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 applicants who 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 the Company Commercialization Awards is to finance the development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will provide companies or limited partnerships located in Texas, or those that are willing to relocate to Texas, with 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 award is intended to support companies undertaking product research and development in Texas with Texas-based employees. In determining eligibility for this award, 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 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 applications) should be the intent to develop products that would eventually be approved for marketing for the diagnosis, prevention, and/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 is set on the amount of funding that can be requested. The maximum duration of this award is 3 years; renewal applications will be accepted. 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 State 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.

6. KEY DATES

RFA

RFA release	July 23, 2010

Application

Online application opens	September 1, 2010, 7 a.m. Central Time
Applications due	September 30, 2010, 3 p.m. Central Time
Application review	November 2010-March 2011

Award

Award notification	March 2011
Anticipated start date	May 2011

7. ELIGIBILITY

- The applicant must be a Texas-based entity or an entity located in Texas at the time a contract for a Company Commercialization Award is executed. This award is intended to support companies undertaking product research and development in Texas with Texas-based employees. In determining eligibility for this award, 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 applicant may submit only one application under this RFA during this funding cycle.
- An applicant may resubmit a revised application that was previously not funded (see Section 9.3.8).
- Only one co-applicant may be included on the application. Collaborators should have specific and well defined roles.

- Funding will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas State 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 familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 10. 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 evaluated using a three-stage process: (1) Commercial review, (2) scientific peer review, and (3) an indepth due diligence process including, but not limited to, intellectual property, management, regulatory, manufacturing, and market assessments. Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT will require the submission of a detailed business plan and a comprehensive research plan (see Sections 9.3.6 and 9.3.7, respectively). The business and research plans will be reviewed by CPRIT's Commercialization Review Council and by a scientific research committee for commercial viability, product feasibility, scientific merit, and therapeutic impact. Each application review is conducted confidentially, and all council and committee members are required to sign nondisclosure statements regarding the contents of the applications. All members will operate under strict conflict of interest prohibitions. Under no circumstances should personnel from an applicant organization initiate contact with any member involved in the review process (with the exception of CPRIT staff) regarding the status or substance of the application. Violations of this prohibition will result in the administrative withdrawal of the application.

8.2. Commercialization Review Criteria

Commercial review of applications will be based on the following criteria:

Product: Is there demonstrated 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?

Market Plan: Is there a realistic assessment of the market size and expected penetration? Has management adequately assessed potential competitors and described how the company's offering will successfully compete with them?

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?

Management and Staffing: 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?

Budget and Duration of Support: Is the budget and duration appropriate for the proposed work? Does the amount requested enable the applicant 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?

8.3. Scientific Review Criteria

8.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit of the work proposed in the application. Concerns regarding any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed work. The primary criteria are:

Significance and Impact: Will the outcomes of this CPRIT-funded work result in the development of innovative products with significant commercialization potential? Will the outcome substantially impact the diagnosis, treatment, or prevention of cancer?

Research Plan: Is the proposed product, service, and/or infrastructure based on a feasible research framework, hypothesis, and/or goal? Are the methods appropriate and are potential developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the applicant have the appropriate level of management and scientific experience to execute the stated strategy? Does the team have the needed experience

or access to experienced external assistance to accomplish all aspects of the proposed plan? Are the levels of effort of the key personnel appropriate?

Commercial Potential: 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?

Relevance: Will the proposed investment have either a direct or indirect impact on improving outcomes for patients with cancer?

8.3.2. Secondary Criteria

Secondary criteria contribute to the overall evaluation of the application. Concerns regarding these criteria potentially question the feasibility of the proposed research. The secondary criteria are:

Environment: Does the team have the needed facilities and resources to develop the proposed product, service, or infrastructure?

Budget and Duration of Support: Is the budget appropriate for the proposed work? Does the amount requested enable the applicant 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?

9. SUBMISSION GUIDELINES

9.1. Online Application Receipt System

Applications will be accepted beginning at 7 a.m. Central Time on September 1, 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.** Submission of an application is considered an acceptance of the terms and conditions of the RFA.

9.2. Application Submission Deadline

All applications must be submitted by 3 p.m. Central Time on September 30, 2010.

9.3. Application Components

9.3.1. Commercialization Review Fee

All applicants must submit a fee of $1,000 for commercialization review. Payment should be made by check or money order payable to CPRIT; the application ID and the name of the submitter must be indicated on the payment. All payments must be postmarked by the application submission deadline and mailed to:

Cancer Prevention and Research Institute of Texas
P.O. Box 12097
Austin, TX 78711

9.3.2. Significance Statement (2,500 characters)

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

9.3.3. Laypersons' Summary (1,500 characters)

Provide a laypersons' summary of the proposed project. Describe, in clear, nontechnical terms the overall goals of the work, the type of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

9.3.4. Scope of Work and Milestones (1 page)

Outline the specific goals of the 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.

9.3.5. 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.

9.3.6. Business Plan (25 pages)

Provide a business plan that includes a description of: (i) the business objective(s); (ii) the product(s) and market(s); (iii) intellectual property; (iv) financial projections; (v) regulatory plan(s); (vi) risk analysis; (vii) the founders, management team, and key professionals; (viii) resources required (both product development and relocation expenses); and (ix) appendix of supporting documents.

9.3.7. Research Plan (10 pages)

The research plan should describe: (i) the scientific basis for the product(s), including feasibility studies and results; (ii) experimental design, including methods and anticipated results; (iii) potential problems or pitfalls; and (iv) alternative approaches. Preliminary data and results are encouraged. The plan should also include an outline of anticipated major milestones to be tracked in the proposed program.

9.3.8. 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 project 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 1 page of the 25-page Business Plan and/or up to half a page of the 10-page Research Plan to outline the approach to the resubmission. *All resubmission applications must conform to the structure and guidelines outlined in this RFA.*

9.3.9. Supplemental Documents

References: Provide a concise and relevant list of publications/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. The budget must be aligned with the proposed milestones. 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 State 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.
- The annual salary that an individual may receive under a CPRIT award for FY 2011 is $200,000. In other words, an individual may request salary proportional to the percent effort up to a maximum of $200,000. Salary does not include fringe benefits. CPRIT FY 2011 is from September 1, 2010 through August 31, 2011.

Biographical Sketches: Applicants should provide a biographical sketch for each member of the senior management and scientific 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 Corporate Market Capitalization: Describe the company's existing sources of capital and the investors' list.

Organizational/Collaborator Support and/or Other Certification: Applicants may provide letters of organizational support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 5 pages may be provided.

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.

10. AWARD ADMINISTRATION

Texas State law requires that CPRIT research awards be made by contract between the applicant and CPRIT. Texas State 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.

Project Economics Sharing: Recipients should also be aware that the funding award contract will include a revenue sharing agreement and 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. 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 organizations, not to individuals. Applicants who change their organizational affiliation during the time period of the award must submit a written request to CPRIT to transfer the award to the new organization.

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 State law requires the CPRIT award recipient organization to demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the development plan that is the subject of the award.

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 and commercialization aspects of applications.

Dates of Operation: July 23, 2010 to September 30, 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

12.2. 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