CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA C-12-COMP-2

Company Commercialization Awards

FY 2012

Fiscal Year Award Period
September 1, 2011–August 31, 2012

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RFA VERSION HISTORY

Rev 6/30/11 RFA release

1. KEY POINTS

This award mechanism is governed by the following restrictions:

- Company Applicants must be Texas-based companies that have already received at least one round of professional institutional investment (i.e., Series A financing).
- Recipient companies must currently have or must commit to the following: Headquarters and registration in Texas, the majority of staff residing in or relocated to Texas, and use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-State entities.
- Of the total program budget, the Cancer Prevention and Research Institute of Texas (CPRIT) will contribute $2.00 for every $1.00 contributed, in matching funds, by the Company. The demonstration of available matching funds must be made at the time the award contract is executed, not necessarily when the application is submitted.
- Funding will be tranched and will be tied to the achievement of contract-specified milestones.
- Funding award contracts 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.

2. ABOUT CPRIT

The State of Texas has established 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.

3. 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 (e.g., 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.

4. 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 and headquartered 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 that will be staffed with a majority of Texas-based employees, including C-level executives.

5. 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.

6. FUNDING INFORMATION

This is a 3-year funding program with an opportunity for renewal after the term expires. Financial support will be awarded based upon the breadth and nature of the development program proposed. While requested funds must be well justified, there is no limit on the amount that may 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 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. Texas State law limits the amount of awarded 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).

Consistent with statutory mandate, of the total program budget, CPRIT will contribute $2.00 for every $1.00 contributed, in matching funds, by the Company. The demonstration of available matching funds must be made at the time the award contract is executed, not necessarily when the application is submitted. The commitment can be made on a year-by-year basis.

7. KEY DATES

RFA release	June 30, 2011
Online application opens	July 28, 2011, 7 a.m. Central Time
Applications due	August 25, 2011, 3 p.m. Central Time
Application review	September 2011–March 2012
Invitations to present sent	by October 15, 2011
Feedback sent if not invited	by October 15, 2011
Presentations to CPRIT*	October 24 and 25, 2011
Notified if referred for scientific review	by November 15, 2011
Feedback sent if not referred	by November 15, 2011
Notified if referred to due diligence	by December 15, 2011
Feedback sent if not referred	by December 15, 2011
Award notification	by March 30, 2012
Anticipated start date**	May 1, 2012

* All Applicants who wish to be considered are requested to reserve these presentation dates until notified.

** Start date is contingent upon completion of contract negotiations.

8. ELIGIBILITY

- Applicants must be Texas-based companies that have already received at least one round of professional institutional investment (i.e., Series A financing).
- Recipient companies must currently have or must commit to the following: Headquarters and registration in Texas, the majority of staff residing in or relocated to Texas, and Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-State entities. 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 revise and resubmit a previously nonfunded application only once (see Section 10).
- 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 11. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

9. APPLICATION REVIEW

9.1. Overview

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 (see Section 10.3.6) and a comprehensive scientific plan (see Section 10.3.7). The plans will be reviewed by CPRIT's Commercialization Review Council (CRC) and also by a scientific research committee for commercial viability, product feasibility, scientific merit, and therapeutic impact.

Funding decisions depend on a three-step review process:

1. **Commercialization Review**: All eligible applications will be evaluated by the CRC. Members of the CRC have extensive experience with the business and entrepreneurial aspects of the pharmaceutical and biotechnology industries. These individuals are also qualified to evaluate the scientific components of the application.
2. **Scientific Review**: A subset of applications that passes commercialization review will be referred for an independent and extensive scientific review, which is considered the first aspect of the due diligence review process. Scientific reviewers with the appropriate expertise will be chosen from a large pool of leading experts in the field. The research plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by this highly qualified group. To the extent possible, the research plan should be driven by data.

3. **Due Diligence Review**: A subset of applications that passes scientific review will be referred for additional in-depth due diligence, including—but not limited to—intellectual property, management, regulatory, manufacturing, and market assessments.

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.

9.2. Commercialization Review Criteria

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

9.2.1. Primary 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 an 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?

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?

9.2.2. Secondary Criteria

Budget and Duration of Support: Are the budget and duration appropriate for the proposed work? Will 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?

9.3. Scientific Review Criteria

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

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? How would competing products or services affect the value of the proposed offering?

Scientific 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?

10. SUBMISSION GUIDELINES

Applicants are advised to carefully review all instructions in this section before submitting an application. Applications that are missing one or more components, exceed the specified page or word limits, or do not meet the eligibility requirements listed above will be administratively rejected without review. Applicants may resubmit a previously nonfunded application only once. Applicants who choose to resubmit should carefully consider 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. A 1-page summary of the approach to the resubmission should be included (see Section 10.3.3). Resubmitted applications will be assigned to reviewers who did not review the original submission. Reviewers

of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

10.1. Online Application Receipt System and Application Submission Deadline

Applications will be accepted beginning at 7 a.m. Central Time, on July 28, 2011 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. All applications must be submitted by 3 p.m. Central Time on August 25, 2011.

10.2. 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

10.3. Application Components

10.3.1. Significance Statement (2,500 characters)

Describe specifically how the proposed project would support CPRIT's mission (see Section 2). Would it fill a needed gap? Would it synergize with Texas-based resources? Describe the overall goals of your work, the type(s) 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. Clearly address how the Company's work, if successful, will have a major impact on the care of patients with cancer.

10.3.2. Layperson's Summary (1,500 characters)

Provide an abbreviated summary of the significance statement for a lay audience using clear, nontechnical terms. 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.

10.3.3. Resubmission Summary (1 page)

If this is a resubmission, upload a summary of the approach, including a summary of the Applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

10.3.4. Executive Summary (2 pages)

Provide an executive summary that clearly explains the product, service, technology, or infrastructure proposed; competition; market need and size; 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.

10.3.5. Slide Presentation (15 pages)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with one slide filling each landscape-orientation page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.3.6. Business Plan (15 pages)

Provide a business plan covering all of the topics below in the order shown. Successful Applicants will make thoughtful, careful, and economical use of the limited space. Note that, if the Company is selected to undergo due diligence, information to support a full intellectual property review will be requested at that time.

A. **Introduction**: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer care that will be addressed. Describe the label claims that the Company ultimately hopes to make, and briefly describe the plan to gather evidence to support these claims. Include the minimum level of detail required to provide a context for the rest of the business plan. Cross-reference sections in the scientific plan where further details may be found.

B. **Products and Markets**: Provide a brief description of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care.

C. **Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities, driven by interactions with the FDA if possible.

D. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated.

E. **Current and Pending Support**: Describe all funding sources. Provide a complete and detailed capitalization table, which should include all parties who have investments, stock, or rights in the Company.

F. **Financial Projections**: Provide a detailed sources and uses analysis of the development plan, focusing on the achievement of specific milestones.

G. **Resources Requested**: Include resources needed for product development and for any relocation expenses.

H. **Scope of Work and Milestones**: 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.

I. **Key Personnel**: For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications.

J. **Organizational Commitment to Texas**: Describe how CPRIT funding of the Applicant's Company would benefit the State of Texas. For example, describe how the Company would create high-quality new jobs in the State and/or recruit out-of-State talent, and mention any Texas-based subcontractors and suppliers that would be used and any other unique, Texas-based resources that would be leveraged.

10.3.7. Scientific Plan (10 pages)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the Company's ideas. Describe the label claims that the Company ultimately hopes to make, and describe the plan to gather evidence to support these claims. Outline the steps to be taken during the proposed period of the award, including the design of the translational or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

10.3.8. Biographical Sketches of Key Scientific Personnel (8 pages)

For the purpose of scientific review, provide a biographical sketch for up to 4 key scientific personnel 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. (For the purpose of commercialization review, information on the members of the senior management and scientific team from the "Key personnel" section of the Business Plan will be used [see Section 10.3.6]).

10.3.9. Appendix (optional; up to 10 pages)

Material that does not fit in, or is not appropriate for, the application components above may be included in an optional appendix of up to 10 pages. **Note that reviewers may choose not to read the appendix. Therefore, all essential information should be presented elsewhere in the application**.

10.3.10. 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 2012 is $200,000. In other words, an individual may request salary proportional to the percentage effort up to a maximum of $200,000. Salary does not include fringe benefits. CPRIT FY 2012 is from September 1, 2011 through August 31, 2012.

11. 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. As mandated by State law, indirect costs are limited to a maximum of 5 percent of the total award. These contract provisions are specified in CPRIT's administrative rules, which are available at www.cprit.state.tx.us.

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.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas State law requires the CPRIT award recipient organization to demonstrate that it has $1.00 in matching funds for every $2.00 from CPRIT. Matching funds need not be in hand when the application is submitted. However, matching funds must be obtained before CPRIT funds will be released for use.

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:	June 30, 2011 to August 25, 2011
Hours of operation:	Monday through Friday, 7 a.m. to 4 p.m. Central Time
Tel:	866-941-7146
E-mail:	CommercializationHelp@CPRITGrants.org

13.2. Commercialization Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Commercialization Review Office.

Tel:	512-305-8484
E-mail:	CommercializationHelp@CPRITGrants.org
Web site:	www.cprit.state.tx.us