



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

**REQUEST FOR
APPLICATIONS
RFA C-12-INCUB-1**

**Texas Life Science Incubator
Infrastructure Awards**

2011–2012

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

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RFA VERSION HISTORY

- Rev 5/11/11 RFA release
- Rev 6/1/11 Revised Section 12, Contact Information
- Changed HelpDesk e-mail address
- Rev 8/29/11 Revised Section 6, Key Dates, and Section 9.2, Application Submission Deadline
- New submission deadline: September 22, 2011
- Revised Section 12.1, HelpDesk
- New Dates of Operation: through September 30, 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) seeks infrastructure program applications to create and sustain one or more life sciences incubators in Texas. The life sciences incubator's primary objectives are to foster a more entrepreneurial life sciences culture in Texas and to cultivate Texas-based life sciences start-up businesses focusing on the development of innovative oncology products and technologies. Applicants are encouraged to partner with one or more teams (academic institutions, private and public business consortia, established life sciences companies, and the investment community) to provide expert business and technical assistance to the incubator, with one institution taking leadership responsibility for the program. CPRIT funds are intended to support the creation and early growth of the life sciences incubator in conjunction with other State and local funding sources, including private sector, philanthropic, and/or other outside support.

3. MECHANISM OF SUPPORT

The goal of the Texas Life Sciences Incubator Infrastructure Award is the development or enhancement of incubator organizations that will provide valuable programs and services in Texas to enhance the ability to commercialize innovative, new products for the diagnosis, treatment, or prevention of cancer and to establish infrastructure that is critical to the development of a robust life sciences industry in the State. Supported incubator programs should promote a culture that rewards risk-taking and entrepreneurial projects, fosters collaboration and cooperation among different Texas institutions and organizations, and creates an environment of mentoring and shared experience and skills to foster the development of new entrepreneurs. This award is intended to support incubator organizations located in the State (with Texas-based employees) providing incubator services to Texas-based translational research projects and startup companies. Specific incubator services that may be supported by this award include but are not limited to:

- Sharing resources for early-stage oncology company formation, including core legal, accounting, communication, office functions, IT support, and basic office/meeting space.
- Assisting early-stage oncology companies in seeking funding from outside sources, including State and Federal grants, venture capital, and strategic investors.
- Creating a network of validated service providers (e.g., contract research organizations [CROs]) and negotiation of streamlined contracts and attractive rates for drug development functions and regulatory, clinical, and preclinical services.
- Creating and maintaining a network of scientific advisors at adjacent institutions that incubator companies may access for technical expertise.
- Developing and delivering programs to educate potential entrepreneurial leaders in the Texas biomedical community on company formation, business planning, and real-world advice on fundraising.
- Working to lower barriers between academia and industry in the community to allow academicians to pursue commercial ventures without sacrificing academic careers.
- Educating the investment community on CPRIT opportunities, including promising CPRIT-funded projects and portfolio companies within Texas.
- Maintaining relationships with institutional investors and, to the extent possible, providing market feedback to shape the entrepreneurial projects that community members pursue.

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- Coordinating with technology transfer organizations within the area to simplify and streamline licensing processes.
 - Providing resources for incorporation, including reasonable expenses associated with forming or relocating a company, negotiating licensing terms, performing intellectual property reviews, and developing a business plan.

4. OBJECTIVES

Despite the presence of leading medical research centers, clinical care providers, and academic institutions in Texas, the State has not yet developed into a global destination for life science entrepreneurship. The long-term objective of this award is to establish Texas programs and infrastructure encouraging life sciences entrepreneurship that will directly support the development of more commercially oriented therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, and services. The life sciences incubators would play a guiding and coordinating role statewide, ensuring that existing and developing assets are matched most effectively against innovative development projects and that new infrastructure investments are directed to the greatest effect possible.

5. FUNDING INFORMATION

There is no limit on the amount that may be requested; however, requested funds must be well justified and reasonable. Applications that do not meet the reasonableness requirement will not be favorably received. The maximum duration of this award is 3 years; noncompetitive renewal applications may be accepted for an additional 2 years. Funding will be milestone driven. Funds may be used for salary and fringe benefits, research supplies, equipment, preclinical and clinical trial expenses, intellectual property acquisition and protection, external consultants and service providers, and other appropriate development costs subject to certain limitations set forth by Texas State law.

If the incubator organization is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support only activities directly related to cancer product development. Requests for funds to support construction and/or renovation may be considered under very compelling circumstances for projects that require facilities that do not already exist in the State of Texas. These requests will be subject to statutory limitations imposed by CPRIT authorization.

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

6. KEY DATES

RFA

RFA release May 11, 2011

Application

Online application opens May 20, 2011, 7 a.m. Central Time

Applications due September 22, 2011, 3 p.m. Central Time

Application review October 2011

Award

Award notification November 2011

Anticipated start date December 2011

7. ELIGIBILITY

- The applicant must be a Texas-based entity with Texas-based employees. Out-of-state entities are eligible to apply, but all award recipients must be located and operating in Texas at the time a contract for a Texas Life Sciences Incubator Infrastructure Award is executed. To deliver on the mission of educating and advancing nascent life sciences entrepreneurs, preference will be given to applications that locate the incubator at an existing academic institution in close proximity to one or more leading institutions of medical education or centers for clinical research and at least one nationally recognized business school.
- The applicant must have demonstrated expertise in working successfully with entrepreneurs, inventors, investors, funding agencies, and/or regional development agencies.
- The applicant should be working with teams capable of providing skilled business, regulatory, and technical expertise and is encouraged (but not required) to partner with an academic institution supporting potentially high-impact cancer studies.
- 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.

- Proposed life sciences incubator projects are not required to focus solely on oncology-related product development. However, to the extent that the proposed incubator organization provides programs or services to entities developing non-cancer-related products, costs related to such programs or services are not eligible to receive funds from CPRIT under any circumstance.
- An applicant may submit only one application under this RFA during this funding cycle.
- 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 an 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

Applications will be assessed based on evaluation of the quality of the proposed accelerator/incubator organization and the potential for significant contribution toward the education and advancement of life sciences entrepreneurship in Texas. CPRIT will require the submission of a detailed business plan. The business plan will be reviewed by CPRIT's Commercialization Review Council for commercial viability, program feasibility, and the strength and breadth of proposed collaborations with leading institutions of medical education, centers for clinical research, and leading national business schools. 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.

Applicant's Qualifications and Experience: Does the applicant have the relevant and necessary background and experience working with life science business startups and the ability to provide expert business and technical assistance to new companies? Does the applicant have experience leading, advising, or funding an innovative life sciences company? Does the proposed team include a balance of entrepreneurial talent, business acumen, and scientific expertise? Does the team demonstrate resourcefulness, cooperation, and teamwork? Does the applicant propose to include team members with various specialties, such as finance, accounting, legal, business development, marketing, and production?

Scope of Services: Is the scope of services comprehensive and likely to result in success? Does the statement of work outline a well-conceived course of action? Are the proposed staff allocations and schedules reasonable? Is the project well conceived and sound?

Evaluation Plan and Expected Benefits: Does the applicant propose a sound program evaluation plan, including scientific review, commercial viability, milestone measures, expected deliverables, and required accomplishments? Will activities bring additional life sciences commercialization activity to Texas? **Is this proposal in the best interest of the State of Texas?**

Environment: Have the applicant and proposed team(s) identified the needed facilities and resources to contribute to a successful life sciences organization?

Budget and Duration of Support: Are the budget and duration appropriate for the proposed work? Would 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 incubator organization to a point where, if the results are positive, it is likely that the organization 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 May 20, 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 this RFA.

9.2. Application Submission Deadline

All applications must be submitted by 3 p.m. Central Time on September 22, 2011.

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 incubator organization, if successful, will have a major impact on the development of startup life sciences businesses based in Texas (with a focus on the creation of innovative oncology products and technologies) and contribute toward making Texas a preeminent global destination for life sciences entrepreneurship. Include clear metrics of success, such as business creation, commercialized products, wealth generation, and value to Texas.

9.3.3. 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.

9.3.4. Scope of Work and Milestones (3 pages)

Outline the specific goals of the project. Prepare a master schedule showing starting and completion times for each task (item) in terms of weeks or months; e.g., Month 1 from project start, Month 2 from project start. Identify anticipated major milestones to be tracked, reports, and other deliverables as well as meetings. The schedule should cover a 3-year period. Prepare an organizational chart listing all key personnel and showing their roles or responsibilities, including any subcontractors and other sponsors involved in the project. Explain how coordination with all project participants will be accomplished. Timelines will be reviewed for reasonableness and expected deliverables, 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)

Briefly describe the life sciences incubator and the timeframe for getting the center up and running. The description should include the staffing structure, the board of directors (BOD) and/or advisors, the range of business and technical services that will be made available, and the proposed site location and its accessibility to life sciences entrepreneurs, researchers, and the investment community. The description should include the incubator's marketing plan.

9.3.6. Business Plan (25 pages)

Provide a business plan that includes a description of: (i) the business objective(s); (ii) the anticipated product(s) and market(s); (iii) financial projections; (iv) risk analysis; and (v) resources required (both product development and relocation expenses); and (vi) an appendix of supporting documents. The appendix is included in the limit of 25 pages.

As part of the plan, the application must identify the incubator executive director who will be responsible for running the day-to-day operations of the center, and include sufficient detail about the individual's background, credentials, and experience for evaluation of his or her qualifications to successfully establish and operate a new incubator center. The executive director must possess core strengths in business development and in linking inventors of new technologies with investors and should have a strong network within the Texas life sciences community.

The plan should also identify incubator team members and advisors, including plans for creating a strategic investment committee (SIC) whose charge would be to select programs to be supported by the incubator center. Specifics on the SIC members and process will be a critical component of the review criteria. CPRIT has a vested interest in making sure that the incubator project selection process is gold standard, conflict free, and will result in picking the very best projects for investment of State dollars. Provide background information on the incubator team members' various specialties, such as scientific, finance, accounting, legal, business development, marketing, and production. Biographies for all identified team members should be provided. Entrepreneurial background involving the following types of activities is also desired: Life sciences startups, drug development, medical device development, life sciences tools development, and life sciences commercialization. The application may include a plan to subcontract for technical services through one or more CROs. If specific CRO partners have been identified, include resumes for key personnel; detail experience, qualifications, and specific services provided; and, as possible, reference customers.

In addition, the plan should identify the proposed timeline and strategy to recruit and seat a BOD for the incubator. The BOD should offer insight or experience not available from the incubator executive director and staff. Further, the BOD will have responsibility regarding a strategic investment committee that will evaluate and approve it.

9.3.7. Organizational/Collaborator Support and/or Other Certification (5 pages)

Applicants may provide letters of organizational support, collaborator support, and/or other certification documentation relevant to the proposed project.

9.3.8. 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.

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- 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. Guidance regarding indirect cost recovery can be found in CPRIT's administrative rules, which are available at www.cprit.state.tx.us.

This information will be entered into forms in the budget section of the online application receipt system.

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: Applicants also should 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 will summarize the progress made toward the research goals and will 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 \$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.

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 is not in a position to answer questions regarding scientific and commercialization aspects of applications.

Dates of operation: May 11, 2011, to September 30, 2011
Hours of operation: Monday through Friday, 7 a.m. to 4 p.m. central time
Telephone: 866-941-7146
E-mail: CommercializationHelp@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.

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