



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

**REQUEST FOR
APPLICATIONS
RFA C-12-INCUB-2**

**Texas Life Science Incubator
Infrastructure Awards**

2011–2012

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

TABLE OF CONTENTS

1.	ABOUT CPRIT	4
2.	EXECUTIVE SUMMARY	4
3.	MECHANISM OF SUPPORT	5
4.	OBJECTIVES.....	6
5.	FUNDING INFORMATION	6
6.	KEY DATES	7
7.	ELIGIBILITY.....	8
8.	APPLICATION REVIEW	9
	8.1. Outline	9
	8.2. Review Criteria.....	9
9.	SUBMISSION GUIDELINES	13
	9.1. Online Application Receipt System and Application Submission Deadline.....	13
	9.2. Commercialization Review Fee.....	13
	9.3. Application Components	13
	9.3.1. Significance Statement	13
	9.3.2. Layperson’s Summary.....	14
	9.3.3. Scope of Work and Milestones	14
	9.3.4. Executive Summary.....	14
	9.3.5. Business Plan.....	14
	9.3.6. Organizational/Collaborator Support and/or Other Certification	15
	9.3.7. Budget and Justification.....	16
10.	AWARD ADMINISTRATION.....	16
11.	REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	17
12.	CONTACT INFORMATION	17
	12.1. HelpDesk.....	17
	12.2. Commercialization Programmatic Questions.....	17

RFA VERSION HISTORY

- Rev 9/29/11 RFA release
- Rev 2/2/12 Updated Section 2, Executive Summary
- Expanded description of purpose
- Updated Section 6, Key Dates
- Extended application receipt deadline
 - Added dates for Applicant presentations
- Updated Section 8.2, Review Criteria
- Provided more detail on how applications will be evaluated

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 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. In addition, this RFA seeks to create, sustain, or expand programs within for-profit companies or non-profit institutions focused on the discovery or development of innovative oncology medicines. A special emphasis will be given to organizations capable of bridging the critical “translational gap” by leveraging both preclinical expertise (e.g., in cancer genomics, biology, drug discovery, and pharmacology) and clinical trial expertise. Applicants with the ability to cultivate a collaborative and entrepreneurial Texas ecosystem are especially encouraged to apply.

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.

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- 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.
 - 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.

CPRIT supports a virtual management company (Texas BioAlliance) available to work with those who receive an Incubator award. CPRIT encourages close collaboration with Texas BioAlliance in those cases deemed advisable. Information regarding accessing Texas BioAlliance will be provided at the time of grant award.

6. KEY DATES

RFA release	September 29, 2011
Online application opens	October 6, 2011, 7 a.m. Central Time
Applications due	March 15, 2012, 3 p.m. Central Time
Application review	April 2012 – July 2012
Invitations to present sent	by May 1, 2012
Feedback sent if not invited	by May 1, 2012
Presentations to CPRIT*	May 21 and 22, 2012
Award notification	by July 31, 2012
Anticipated start date**	September 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.

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.
- 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 development 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. Review Criteria

Review of applications will be based on the following criteria.

Management Team

- 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?
- Are there lean, full-time incubator staff engaged for day-to-day management? Staff may include the following typical roles: President or executive director (proven commercialization and prior incubator experience, demonstrated networker and collaborator); business/administrative personnel (legal and finance roles often outsourced); marketing/communications personnel (often outsourced); personnel to educate member companies on commercialization; and executives-in-residence (EIR) (to serve as

mentors/advisors for member companies). Some of these roles may be outsourced; however, roles pertaining to leadership, operations oversight, and business development are usually maintained by 100 percent dedicated experienced professional staff. How will accountability be maintained?

- How will alliances be generated so as to leverage experience in the community? Alliances are critical. Academic/medical institutions, commercial entities (e.g., venture capital and intellectual property attorney firms) and device/biopharmaceutical ventures are examples of alliances that can feed essential quality technologies into the incubator deal flow, offer resources for member company management, and/or provide funding support. Multiple alliances are especially important in Texas, as it is not expected that any one institution can produce enough technology in oncology to support an incubator. These significant alliances can bolster and support incubator efficiency and productivity while allowing incubators to maintain streamlined operations via decisions assigned to the accountable staff or board.
- Is there an appropriate Incubator Board of Directors? The composition should include business, commercial, and scientific leadership. The board's basic function is for fiduciary oversight for the incubator. The board should also be involved to insure smooth access to technology and help streamline the technology transfer process.
- Is there an appropriate Investment Advisory Board/Council/Committee? The composition should include commercial, scientific, academic, and industry leadership; it may also include venture capitalists, intellectual property attorneys, marketers, clinicians, and preclinical/product developers. Its basic function is for strategic advisement on technology investment for the incubator. The most important advice may come from a source willing and able to fund or acquire the technology.

Deal Flow

- What kind of infrastructure is proposed to provide access to high quality deals? How will the quality of the proposals be assessed? Many high-quality proposals must be vetted to produce one new company. Is there an aligned independent advisory board, containing a mix of commercial, development and scientific expertise, assigned by the incubator to vet opportunities? Is there marketing to reach sources and help drive awareness of the incubator's offerings?
- What is the process to provide access to high-quality deals, and what is the exit strategy for

the deals? How will technology flow into, through, and out of the incubator? What general milestone-driven metrics will be used to assess deals?

Incubator Productivity

- Is anticipated productivity outlined for the first 3 years?
- What metrics will be used for quantitatively and objectively measuring success?
- How will the incubator initially focus on early wins and identify lower risk projects with a higher probability of success?
- 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?

Member Company Basic Support Factors

- Have the Applicant and proposed team(s) identified the needed facilities and resources to contribute to a successful life sciences organization? Is there space or access to space, including office space, wet laboratories, and a conference room for staff and onsite potential investor visits?
- 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?
- Is there a description of management alignment for when new management is required for technologies, whether via an assignment from the outside or alignment of an EIR or mentor with the current management?
- Is a general funding support process outlined? How will (capped) seed funding and advice on additional fundraising be provided? What is the plan for the incubator to “graduate” successful companies as cost-effectively as possible?
- What approach is outlined for education, advising, and mentoring outreach programs? Business strategies may include educating and/or advising on company formation, business planning, and fundraising via internal and community sources, and provision of coaches/mentors via EIRs and other sources. Development strategies may include educating and/or advising on commercialization strategies/tactics via internal and community sources, and provision of coaches/mentors via EIRs and other sources. Networking programs may

include seeding informal research, development, and commercial alignments as well as bolstering academic-industry collaborations in business and social forums. Are there plans for the incubator to collaborate with existing community resources while building its programs?

Marketing

- Is there a plan for marketing programs to drive awareness of the incubator offerings and promote a sustained deal flow?
- Is there recognition of market segment alignment and outlined plans for active alliance with device, pharmaceutical, and biotech company ventures; other regional/State/national incubators; venture firms, intellectual property attorneys and contracted development services; regional/State/national industry professional organizations?
- Will the Applicant network effectively with sources and/or investors for technologies, with potential management for new member companies, or with partners for collaborative deals to optimize new technologies?

Budget and Duration of Support:

- Are the budget and duration of support 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?
- Has a total funding plan been developed to leverage all sources of capital (i.e., SBIR, STIR, and specialty grants)?

Economic Sustainability

- Is there a reasonable budget to establish the incubator, maintain operations, and instill member company payment arrangements? This is likely to include standard first year set-up cap expenditures plus the ongoing operational expenses (e.g., building lease, equipment lease, insurance, consultants, payroll vendor). It may or may not include breakdown for

performance incentives with bonus payments on a milestone basis.

- Are there reasonable terms for equity ownership, royalties, and/or compensation with regard to the incubator and its member companies? Whether an incubator is for-profit or not-for-profit, there may or may not be an equity stake arrangement in member companies.
- How will the incubator exercise investment discipline to avoid outsized project risks? The approach might include the following factors: Caps on total investment in member companies; limits for length of stay within the incubator for a member company; consistent definition, tracking, and activation of go/no go decisions on projects; and requirements for matching funds from venture investors.

9. SUBMISSION GUIDELINES

9.1. Online Application Receipt System and Application Submission Deadline

Applications will be accepted beginning at 7 a.m. Central Time on October 6, 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. All applications must be submitted by 3 p.m. Central Time on March 15, 2012.

9.2. 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; electronic payments are not acceptable. 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. Application Components

9.3.1. 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.

9.3.2. 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.

9.3.3. 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.

9.3.4. 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.

9.3.5. Business Plan (25 pages)

Applicants are advised to consider the review criteria (Section 8.2) when developing the business plan.

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.

9.3.6. 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.

9.3.7. 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. 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.

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: October 1, 2011, to March 30, 2012 (excluding public holidays)

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