



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA R-21.2-TCTPA

Texas Clinical Trials Participation Program
Award

**Please also refer to the Instructions for Applicants document,
which will be posted on September 16, 2020**

Applications for this award mechanism are subject to institutional limits.
Applicants are advised to consult with their institution's
Office of Research and Sponsored Programs (or equivalent).

Application Receipt Opening Date: September 16, 2020

Application Receipt Closing Date: January 27, 2021

FY 2021

Fiscal Year Award Period

September 1, 2020-August 31, 2021

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RFA VERSION HISTORY

Rev 08/05/20 RFA release

ARCHIVE

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or 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
- Develop and implement the Texas Cancer Plan.

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions
- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer
- Expansion of access to innovative clinical trials

2. PURPOSE AND RATIONALE

This RFA solicits applications targeting projects to increase the number and diversity of subjects participating in therapeutic cancer clinical trials in Texas by removing the out-of-pocket expenses related to travel to and from clinics, lodging, meals, and any extra childcare, as a barrier to participation for financially burdened subjects.

Many patients enrolled in clinical trials face a substantial travel burden and associated out-of-pocket expenses that discourage them from participating in clinical trials. While cancer centers, philanthropic organizations, and health systems provide some assistance, eg, ACS Hope Lodge, nonclinical expenses remain a significant barrier to clinical trial participation, particularly for those traveling long distances for cancer care.

To address the financial burden associated with the nonclinical out-of-pocket expenses to clinical trial participation, Massachusetts General Hospital Cancer Center developed the “Cancer Care Equity Program (CCEP).” The goal of the CCEP was to ensure that all patients with cancer have access to the best care possible, regardless of their socioeconomic status. The CCEP consisted of 3 key components: (1) community outreach and education to build awareness of available cancer options, especially clinical trials; (2) patient navigation for cancer screening and diagnosis; and (3) a financial assistance program for clinical trial participants. By assisting with travel and lodging costs, the CCEP was associated with increased trial accrual (Nipp et al, *The Oncologist*. 2016;21:467-474) and reduced financial stress experienced by patients and family (Nipp et al, *The Oncologist*. 2019;24:1048-1055). These findings suggest that nonclinical financial concerns represent a barrier to patient participation in clinical trials and underscore the importance of efforts to address these concerns.

CPRIT is undertaking a **Texas Clinical Trials Participation Program (TCTP)** to demonstrate the impact of removing the nonclinical out-of-pocket expenses related to travel to and from clinics, lodging, meals, and any extra childcare, as barriers to participation in cancer clinical trials for financially burdened subjects. The TCTP Award is conceptually based upon the successful Massachusetts General Hospital Cancer Center’s “Cancer Care Equity Program” concept (described above) and is authorized by a recent state law (HB 3147, 86th Texas Legislature) that allows sponsors of cancer clinical trials to reimburse eligible patients for nonclinical expenses associated with participating a clinical trial, including costs for travel,

lodging, parking and tolls, and other costs considered appropriate by the organization (Texas Health & Safety Code, Subtitle B, Title 2, chapter 50). See the Instructions for Applicants (IFA) for specific details regarding allowable costs.

3. PROGRAM COMPONENTS

This Request for Applications (RFA) solicits applications proposing projects to increase the number and diversity of subjects participating in therapeutic cancer clinical trials in Texas by removing nonclinical financial barriers to participation in cancer clinical trials for financially burdened subjects.

3.1. Components responsive to this RFA

Components responsive to this RFA should include the following:

1. Needs assessment that describes the patient population served by the institution and a baseline that will be used to evaluate impact on clinical trial accrual and financial stress experienced by patients and family members eligible to receive support for nonclinical out-of-pocket expenses. This assessment should include information on the number of patients seen at the institution who live outside the local catchment area (>50 miles from the clinic site).
2. Documentation of a clinical trials program that sponsors therapeutic clinical trials available to the targeted population, including baseline metrics of current accrual of the targeted population from the local catchment and from subjects living greater than 50 miles from the institution to available therapeutic clinical cancer trials and demonstration of the ability to reach the priority population.
3. Description of how the program will identify subjects eligible for reimbursement of nonclinical expenses associated with their participation in a therapeutic cancer clinical trial pursuant to V.T.C.A, Health & Safety Code, Subtitle B, Title 2, chapter 50 (<https://statutes.capitol.texas.gov/Docs/HS/htm/HS.50.v3.htm>). See IFA for specific details.
4. The program should include an overview of the process for assessing and recording the economic eligibility of potential subjects, which must meet the requirements of Texas Health & Safety Code Section 50.0003(a).

5. A plan for how the program will engage collaborating physicians and health care providers to notify prospective subjects about the program.
6. The program should include the calculation that will be utilized to determine funding available per subject and the subject's support person. This reimbursement plan may include the following:
 - (a) Reimbursement to subjects is based on financial need. See IFA for suggested guidelines.
 - (b) Reimbursement of nonclinical expenses such as travel costs, lodging, parking, tolls, and childcare costs to allow for trial participation.
 - (c) Reimbursement of expenses identified above to 1 family member, friend, or other person who attends a cancer clinical trial–related visit to support a subject.
7. A plan to evaluate the impact of the program on the participation of the targeted population in therapeutic clinical trials from both inside and outside of the local catchment area and an assessment of impact of the program on financial stress and quality-of-life measures.

3.2. Metrics of success

Metrics of success include the overall accrual of new patient volume to therapeutic clinical trials over baseline data submitted in original grant application in the following categories:

1. Ability of the program to enroll new patient volume representing economically disadvantaged patients to therapeutic trials.
2. Ability of the program to enroll new patient volume representing diverse ethnicity demographics to therapeutic trials.
3. Ability of the program to enroll new patient volume representing diverse geographic demographics to therapeutic trials.
4. Ability of the program to engage new community physicians over the baseline assessment in the overall project.

4. FUNDING INFORMATION

Applicants may request a maximum of up to \$1,500,000 in total costs for a period of 3 years.

Allowable costs include the following:

- Funds may be used for personnel salary and fringe benefits for the Project Director (PD) and additional support staff required to carry out the program functions.
- The program is **required** to use at least 66% of the total costs to reimburse subjects for nonclinical expenses such as travel costs, lodging, parking, tolls, and childcare costs associated with their participation in a therapeutic cancer clinical trial. Reimbursement for participants must be based on financial need, which may include reimbursement to participants whose income is at or below 700% of the federal poverty level (See the IFA for specific definition and reference).
- The program **may** reimburse reasonable ancillary costs as detailed in Texas Health & Safety Code Section 50.0002 to 1 family member, friend, or other person who attends a cancer clinical trial visit in order to support the subject participating in the clinical trial. See IFA for specific details.

Requests for funds to support major equipment, construction, and/or renovation will not be approved under this funding mechanism.

The program must comply with applicable federal and state laws. Participant reimbursements must be reviewed and approved by the institutional review board associated with the clinical trials for which reimbursements are provided.

State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

Pursuant to V.T.C.A., Health & Safety Code, Subtitle B, Title 2, chapter 50, Section 50.0005, reimbursement of eligible costs under this program do not constitute an inducement and is not considered coercion or the exertion of undue influence to participate in a cancer clinical trial.

The reimbursements are meant to accomplish parity in access to cancer clinical trials for financially burdened subjects. See IFA for specific details.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Institutions, organizations, or other entities (including physician groups) that conduct cancer clinical research are eligible to apply; however, a public or private company operating as a clinical research organization (CRO) is not eligible for funding under this award mechanism.
- The PD must be a full-time resident of Texas at the time the application is submitted and during the entire time the grant is active.
- The designated PD will be responsible for the overall performance of the funded project.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in clinical trials analysis and evaluation and who resides in Texas during the time that the project is conducted.
- This award does not allow a Co-PD.
- An institution or organization may submit only 1 application under this RFA.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member (view current Oversight Committee members here: <https://cprit.texas.gov/oversight-committee>).
- The applicant must report whether the applicant institution or organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

- CPRIT grants are awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. All statutory provisions and relevant administrative rules can be found at <https://cprit.texas.gov/about-us/statute-rules-and-grant-policies-guide/>.

6. RESUBMISSION POLICY

Not applicable as this is a new CPRIT RFA.

7. RENEWAL POLICY

Not applicable as this is a new CPRIT RFA.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PD must create a user account in the system to start and submit an application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. The *IFA* document will be available when the application receipt system opens. Applications will be accepted beginning at 7 AM central time on September 16, 2020 and must be submitted by 4 PM central time on January 27, 2021. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended upon a showing of extenuating circumstances. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of the submission deadline must be submitted via email to the CPRIT [Helpdesk](#) within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records. Please note that deadline extension requests are very rarely approved.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *IFA* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in [section 5](#) will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Describe the proposed program including a description of the organizational structure, outcomes of a needs assessment, therapeutic clinical trial capabilities and summary of current therapeutic clinical trials available to the program, the methodology and criteria for the selection of patients to be included in the clinical trials, and the unique qualifications that will enable the applicant to meet the requirements described in [section 3](#) for the program. Discuss special assets that the proposed program will bring to the overall mission of the TCTPA Program.

The abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need in the specific service area. Describe barriers, plans to overcome these barriers, and the priority population to be served.
- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the priority population.

- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of subjects to be enrolled in clinical trials along with the estimated total number of subject support individuals.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a major impact on increasing the number and diversity of subjects enrolled in therapeutic cancer clinical trials.

8.2.2. Layperson’s Summary (2,000 characters)

Provide a layperson’s summary of the proposed program including description of the clinical trial sites and patient population served. Describe, in simple, nontechnical terms, how the program will facilitate access to clinical trials, the type(s) of trials proposed for the program, and the expected impact on patient access to clinical trials and the expected number and diversity of patents being accrued. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the layperson’s summary. The layperson’s summary will also be used by advocate reviewers ([section 9.1](#)) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the award. These goals and objectives will also be used in the initial assessment of the program and in the evaluation of annual progress reports if the award is made. A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. If a baseline has not been defined, applicants are required to explain plans to establish baseline and describe method(s) of measurement.

8.2.4. Timeline (1 page)

Provide an outline (chart) of anticipated major milestones to be tracked in the implementation and evaluation of the program. 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.

8.2.5. Project Plan (15 pages)

Background: Present the rationale behind the proposed services, emphasizing the critical barriers to current service delivery that will be addressed. Identify the service to be implemented for the priority population. Describe the race, ethnicity, age, economic status, and other defining characteristics of the population to be served. Describe the needs assessment process and assessment outcomes and detail how the assessment will be utilized for benchmarking, implementation, and evaluative purposes. Demonstrate the project's access to participating cancer centers or community oncology clinical trials. Include provider(s), partnerships, and agreements (via memoranda of understanding) or commitments (via letters of commitment).

Describe the organization and its track record and success in facilitating an increase in the number and diversity of subjects enrolled in clinical trials. Describe the institution and its commitment to the program, including a description of the catchment areas, the organizational capabilities and clinical research portfolio, and the institution's overall commitment to the award. An institutional letter of support is required.

Goals and Objectives: Concisely *state* the goals and objective of the project. List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. It is expected that steps toward building capacity for the program will be taken and plans for such be briefly described in the application. The applicant should describe the factors that will contribute to the organization's capacity to facilitate sustainability.

Operations Strategy: Discuss how the program will identify, enroll, and reimburse subjects.

- Based on a completed needs assessment, identify the expected number of subjects eligible to participate in the program from the institution's local catchment and the number of the subjects expected to be enrolled who live greater than 50 miles from the clinical trial point of service.

- Discuss plans for use of patient navigators in the recruitment and monitoring of subjects in the program.
- Discuss the process that will be used to validate and reimburse allowable expenses.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Detail the evaluative plan for measuring the program's impact on increasing the number and diversity of the targeted population into therapeutic clinical trials. Describe data collection and management methods, data analyses, and anticipated results.

8.2.6. Human Subjects (2 pages)

Use this section to provide any additional details that may have not been covered in the description of the program. Certification of approval of these plans by the institutional IRB will be required before funding can occur.

8.2.7. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.8. Budget and Justification

Provide a compelling and clear justification of the budget, demonstrating the need for the entire proposed period of support, including salaries and benefits, projected per capita costs of enrolling patients into therapeutic clinical trials and associated costs based on the established baseline assessment, as well as costs associated with the analysis and evaluation component of the project. Applicants may request a maximum up to \$1,500,000 in total costs for a period of 3 years.

Up to one-third of the total budget may be used to support program leadership, patient navigation, administrative costs for reimbursement of subjects, and program evaluation.

Two-thirds of the total costs must be used to reimburse allowable costs. As a guide, the average out-of-pocket expenses of clinical trial participants in similar programs who live locally was \$190/visit or \$2,280 annually (assuming 1 visit/month). When a patient must travel beyond local catchment (> 50 miles) but has no travel companion, the average visit was \$400/visit or \$4,800 annually. When a patient travels beyond local catchment but requires a travel companion (32% of patients request a travel companion), the average visit was \$475/visit or \$5,100 annually.*

Note that patient care costs associated with the conduct of a clinical trial are not appropriate for this mechanism.

Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

The annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award is limited to a maximum of \$200,000. In other words, an individual may request salary proportional to the percent of effort up to a maximum of \$200,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, subject care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

*Data based on Lazarex Cancer Foundation historical averages.

8.2.9. Biographical Sketches for Key Personnel (5 pages each)

Up to 5 biographical sketches including that of the Program PD and key personnel may be provided. Each individual biographical sketch must not exceed 5 pages. The NIH biosketch format is recommended.

8.2.10. Current and Pending Support State

Describe the funding source and duration of all current and pending support for the PD and all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PD and key personnel must be provided.

8.2.11. Institutional/Collaborator Support and/or Other Certification (10 pages)

As outlined in [section 8.2.5](#), applicants are required to provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed program. A maximum of 10 pages for all letters may be provided.

Applications that are missing 1 or more of these components; exceed the specified page, word, or budget limits; or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

8.3. Formatting Instructions

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English
- **Document Format:** PDF only
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point)
- **Line Spacing:** Single
- **Page Size:** 8.5 x 11 inches
- **Margins:** 0.75 inch, all directions
- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.
- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. Include URLs of publications referenced in the application.
Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135: 45–67.

- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

9. APPLICATION REVIEW

9.1. Review Process Overview

All eligible applications will be evaluated using a 2-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council (SRC). In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts, as well as advocate reviewers, using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT SRC based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by the SRC will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, [Texas Administrative Code, Title 25, chapters 701 to 703.](#)

9.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, SRC members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign

nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and SRC members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, [Texas Administrative Code, Title 25, chapters 701 to 703.](#)**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Scientific Review Panel member, or an SRC member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period prior to the opening of CARS. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.3. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

9.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the proposed project expand patient access and geographic proximity to innovative clinical trials? Will the propose program increase the socioeconomic diversity of the patients participating in the applicant’s clinical trials portfolio?

Research Plan: Is the plan based upon a well-described need’s assessment? Does the plan for the proposed project document a process for rapid and efficient access to clinical trials, and does the plan incorporate best practices to ensure timely clinical treatment decisions and the output of high-quality data? Does the applicant have a well-defined plan and an appropriate governance structure to coordinate activities related to the project? Does the plan demonstrate the potential to overcome critical barriers for robust accrual to advance progress in the field? Does the applicant institution have a history of timely activation of clinical trials? Are infrastructure and policies in place to support accrual to clinical trials? Does the institution have active programs to recruit minorities and underserved patient populations to clinical trials? Does the plan include a robust evaluation process? Is the environment and setting of the proposed project adequate to support a robust clinical trial program where 15% of new patients seen will be eligible to enroll on trials?

Technical Expertise: Is there sufficient technical expertise to carry out the duties of the program?

Institutional Commitment: Is there demonstrated strong institutional commitment for support of the program?

Applicant Project Director: Does the applicant Project Director demonstrate the required expertise and experience to lead the project? Has the applicant devoted enough of his or her time (percent effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This is a critical criterion for evaluation of projects for CPRIT support.

9.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the project? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support?

Budget: Is the budget appropriate for the proposed work?

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

10. KEY DATES

RFA

RFA release August 5, 2020

Application

Online application opens September 16, 2020, 7 AM central time

Application due January 27, 2021, 4 PM central time

Application review January 2021 to August 2021

Award

Award notification August 18, 2021

Anticipated start date August 31, 2021

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports.

Such use shall be in accordance with CPRIT's electronic signature policy as set forth in [chapter 701, section 701.25](#).

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in [chapter 703, sections 703.10, 703.12](#).

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, [chapter 703, section 703.20](#).

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals documented in the grant award contract and address plans for the upcoming year. In addition, fiscal reporting and human studies reporting will be required as appropriate.

CPRIT will review annual progress reports and continuation of funding is contingent upon the timely receipt of these reports and documentation of sufficient progress toward completing project goals. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, [chapter 703, section 703.11](#), for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Program Manager for Academic Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.texas.gov