CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-25.2-ECI

Early Clinical Investigator Award

Please also refer to the Instructions for Applicants document, which will be posted on August 28, 2024

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 18, 2024

Application Receipt Closing Date: December 10, 2024

FY 2025

Fiscal Year Award Period

September 1, 2024-August 31, 2025

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RFA VERSION HISTORY

8/28/24 RFA release

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 the area of 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.
- 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 regarding how the Oversight Committee directs the orientation of the agency's funding portfolio.

To accomplish CPRIT's long-term vision, the Oversight Committee has identified these 2025 priorities:

- Investing in the cancer research capacity of Texas institutions through recruitment of cancer scholars, investment in core facilities, and investment in individual investigator awards in all regions of the state;
- Building the Texas cancer life science ecosystem across Texas by bridging discovery and translational research into early-stage company products with high impact on cancer patient care and creating economic development for the State of Texas; and
- Increasing the capacity for Texas to have a significant impact on cancer prevention and early detection, ultimately decreasing cancer incidence and mortality.

Established Principles:

- Scientific excellence and impact on cancer

- Increasing the life sciences infrastructure
- Reducing disparities in cancer incidence and mortality

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 adoption and deployment of evidence-based prevention, early detection, risk assessment and interventions
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer
- Expand access to innovative clinical trials

2. RATIONALE

The number of highly talented individuals entering a career in clinical investigation is decreasing at a time when the excitement and challenge associated with clinical cancer research have never been greater. The reasons for the decline in cancer clinical investigators are many and include the increased demands on clinical faculty to generate clinical revenue and, as a consequence, limited opportunities for clinical faculty to pursue research; the burden of medical school debt that limits a trainee's options for extending training and pursuing an academic career; and the increasingly complex nature of clinical research requiring specialized training not offered by clinical training programs. Consequently, clinical faculty often do not have the opportunity or experience required to initiate a career as a clinical investigator.

There is concern that this decision of oncology-trained clinicians to not pursue careers in patient-oriented research and clinical investigation will seriously impair the ability to translate what has been discovered in the preclinical setting into advances that can benefit patients. Accordingly, there is an urgent need to develop a pipeline of cancer clinicians equipped with the skills and experience necessary to pursue careers in patient-oriented research and capable of leading innovative discovery campaigns through the conduct of clinical trials and **to provide these**

clinical investigators the protected time from service-related clinical responsibilities that is required to develop and conduct investigator-initiated clinical trials.

3. OBJECTIVES

The Early Clinical Investigator Award is designed to provide support for the career development of very promising early-career physicians with specialty training relevant to delivery of cancer care, including therapeutic intervention, early detection, and prevention. Candidates are expected to demonstrate the talent, interest, and commitment to ask questions of patients regarding their diseases and their responses to an intervention that would provide new information about the patient's malignancy and, if the intervention worked, why, or more important, if it did not, why not.

The Early Clinical Investigator Award specifically targets physicians who meet the following criteria:

- **Are within the first 5 years of a faculty appointment at the assistant professor level or equivalent**
- **Have completed specialty training relevant to cancer care, detection, or prevention and are eligible to be certified by their institution to provide patient care in an oncology-related practice**
- **Plan research that involves the conduct of clinical trials involving a therapeutic intervention, early detection, prevention, symptom control, or behavioral interventions**

The CPRIT Early Clinical Investigator Award will do the following:

- Provide cancer physicians early in their academic career the opportunity to develop clinical research skills and to gain experience in advanced methods and experimental approaches needed to become clinical investigators.
- Provide an opportunity to establish a partnership with a laboratory-based collaborator in order to design and conduct correlative studies needed to interpret the outcome of an interventional trial.
- Provide protected time from service-related clinical responsibilities to develop and conduct investigator-initiated clinical trials.

- Increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, capitalizing on basic discoveries and translating them through the conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.

To accomplish these objectives, the CPRIT Early Clinical Investigator Award will provide awards of up to $1,000,000 for up to 5 years to physicians within the first 5 years of a faculty appointment as an assistant professor to acquire additional skills and experience in clinical research and to develop preliminary data that can be used to prepare applications for future research project grants to further both the investigator's career and the CPRIT mission. This award may be used for the following:

- To provide salary support to the candidate
- To support didactic study including enrollment in a degree-granting graduate training program to enhance theoretical and practical skills in design, implementation, and interpretation of data from clinical investigations
- To develop preclinical data and to validate correlative studies with a laboratory-based collaborator
- To support an investigator-initiated clinical trial during the award period

The host institution will be expected to work with each Early Clinical Investigator to design and execute the faculty career development plan consistent with his or her research emphasis. Relevance to cancer and relevance to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

CPRIT encourages the participation of all groups underrepresented in biomedical research.

4. INSTITUTIONAL COMMITMENT

CPRIT Early Clinical Investigator Awards are intended to provide clinical faculty who are early in their first faculty position enough time for scholarly activities to develop the knowledge base, experience, and partnership(s) required of a successful clinical investigator. CPRIT recognizes that Early Clinical Investigators will need to commit time to direct patient care in order to hone their clinical expertise and that the time commitment required will vary depending on the nature

of the individual's clinical practice and level of prior experience; however, the **institution must commit to limiting the service-related clinical duties of the Early Clinical Investigator to no more than 0.5 FTE for the duration of the award. Note that clinical trials research activity may include patient care at clinics conducting clinical trials.**

A critical component of the Early Clinical Investigator Award is the identification of a mentor (or comentors) and the design of a mentoring program that is tailored to the individual's goals and prior experience. The primary mentor should be a clinical and or translational investigator with a strong track record for conducting patient-oriented research. The mentor will be expected to provide an annual progress report that documents progress made toward the goal of independence as a clinical investigator.

5. FUNDING INFORMATION

This award is for **up to 5 years** providing applicants the opportunity to tailor the content and the duration of the award period based upon their individual program. This award is not renewable, although individuals may apply for other future CPRIT funding as appropriate.

Grant funds of up to $1,000,000 (total costs) may be requested. Funding may be used by the Early Clinical Investigator for salary and fringe support (salary up to the CPRIT maximum of $225,000/FTE); for didactic study including enrollment in a degree-granting graduate program, to obtain preclinical data including correlative assay development with a laboratory collaborator; and to support the research project involving an investigator-initiated interventional clinical trial that is a required component of this award.

Applicants are encouraged to design a scholarly training and educational experience that fits the candidate's background and program plan. For example, funds to support didactic study might be emphasized in the first years of the award, and funds to develop correlative assays and to initiate an investigator-initiated clinical trial may be prorated for the later years of the award.

Requests for equipment are not appropriate for this award mechanism except in exceptional circumstances that must be very well justified. Requests for support for faculty mentors are not appropriate for this award. Funds from this award mechanism may not be used to construct or renovate laboratory space.

The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). Candidates are expected to attend CPRIT's conference. CPRIT funds may be used to reimburse registration, travel, and lodging expenses.

Continuation of funding of this award is contingent upon receipt of an annual progress report that documents achievement of the approved training and project milestones (see section 9.2.11).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that provides cancer care and conducts clinical cancer research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- **An institution may submit only 2 applications under this RFA during this funding cycle.**
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- At the time of the application, the candidate must be within 5 years of their first appointment at the assistant professor level or equivalent at an accredited academic institution, research institution, industry, government agency, or private foundation. Exceptions may be granted, if justified, based on a career break due to family obligations or similar circumstances. The candidate must have an MD or DO degree and reside in Texas at the time an award contract is made and for the duration of the appointment.
- The candidate must have oncology subspecialty training or equivalent and be eligible to be certified by their institution to provide patient care in an oncology-related practice. Note: Pathologists and radiologists are eligible for this award.
- Candidates may not hold a Paul Calabresi Career Development Award for Clinical Oncology (K12), a Mentored Clinical Scientist Research Career Development Award (K08) program award, or similar clinical research career development award at the same time as a CPRIT Early Clinical Investigator Award. Individuals who have received a

CPRIT First-Time Tenure-Track Faculty Scholar Award are not eligible for the Early Clinical Investigator Award.

- Individuals who have received an NIH new investigators award (eg, NIH Director's New Innovator Award or NIH Director's Early Independence Award) are not eligible to apply for the Early Clinical Investigator Award.
- Individuals who have received an NIH R01 or equivalent award (such as DOD Congressionally Directed Medical Research Programs Peer Reviewed Cancer Research Program Career Development Award or a CPRIT Individual Investigator Research Award [targeted or nontargeted]) are not eligible to apply for the Early Clinical Investigator Award.
- Candidates must have identified a mentor who is located at the applicant institution and who agrees to supervise the candidate's career development and research experience.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, 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 nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be 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. Significant issues addressed by the CPRIT contract are listed in section 12 and section 13. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once, based on the eligibility criteria of the initial application, and must follow all resubmission guidelines. Note that the resubmission summary should be limited to 1 page, in which the applicant details how the revision has strengthened the application. More than 1 resubmission per application is not permitted. See section 9.2.4.

8. RENEWAL POLICY

This mechanism does not allow renewal applications to be submitted.

9. RESPONDING TO THIS RFA

9.1. 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 is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and apply. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on September 18, 2024 and must be submitted by 4 PM central

time on December 10, 2024. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

9.1.1. 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.

9.2. 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. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 6 will be administratively withdrawn without review.

9.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name and the department and/or entity within the nominator's organization where the candidate is appointed.

9.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the nomination. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer prevention research, early diagnosis, or treatment. 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 in evaluating the significance and impact of the proposed work.

9.2.3. Institutional Commitment (3 pages)

The institutional commitment should be clearly documented in the application in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and the chair of the candidate's department. The following information should be included in the letter:

- Describe the candidate selection process and the organization's commitment to the candidate's career development as a clinical investigator.
- State the total award amount and duration requested.
- Document that at the time the Early Clinical Investigator Award contract begins the candidate will be appointed at the assistant professor level (or equivalent) and will be eligible to provide patient care in a cancer-related discipline at the applicant institution.
- Document that a minimum of 50% of the candidate's effort will be dedicated to individual career development and clinical trials research during the duration of the Early Clinical Investigator Award. Breach of this requirement will constitute grounds for discontinuation of the award.
- Document how the candidate's mentoring plan and research experience were developed and how the institution will oversee the candidate's development as clinical investigator.
- Provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations and leveraging the institution's unique strengths will foster the candidate's career trajectory.

9.2.4. Resubmission Summary (1 page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns. For resubmitted applications, candidates are allowed to be within the first 5 years of a faculty appointment at the assistant professor level or equivalent.

Note: An application previously submitted to CPRIT but not funded may be resubmitted **once** after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a new research plan or modify the original research plan and mark the changes. However, **all resubmitted applications should be carefully reconstructed**; a simple revision of

the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

9.2.5. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate. Only articles that have been published or that have been accepted for publication ("in press") should be cited.

9.2.6. Specific Aims and Sub Aims (1,200 characters per aim and per subaim)

List specific aims and sub aims for each year of the project. These specific aims and sub aims will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. At least 1 specific aim and 1 sub aim are required. Additionally, at least 1 sub aim is required per specific aim. **This section and the following section (9.2.7) must be prepared by the candidate.**

9.2.7. Candidate Information and Career Development Plan (10 pages)

Candidate Background

- Describe the candidate's commitment to an academic career in patient-oriented research.
- Describe the candidate's prior training and how it relates to the goals and long-term career plans of the candidate.
- Describe all the candidate's clinical and other professional responsibilities/activities in the grantee institution beyond the commitment to career development and research and elsewhere and describe their relationship to the proposed activities on this award.
- Describe the candidate's research efforts to this point, including any publications, prior research interests, and experience.

Career Development Plan

- Describe the candidate's mentored research development plan that includes intent to implement an investigator-initiated clinical trial by Year 3 of the award. Include a timeline chart to illustrate this plan.
- Describe any didactic and research experience(s) designed to develop the necessary knowledge and research skills in the scientific areas relevant to the candidate's career goals.

- Demonstrate that the candidate has received training or will participate in courses such as biostatistics, data management, epidemiology, study design, hypothesis development, and drug development including FDA regulatory policies, etc, as well as the legal and ethical issues associated with research on human subjects. **Candidates are encouraged to pursue as part of the Early Clinical Investigator Award an advanced degree-granting program to gain this knowledge**. In addition, candidates may wish to design opportunities to gain experience in clinical investigations as part of an internship or similar arrangement with a pharmaceutical organization.

Research Plan

- Describe a research plan that will lead to the design and implementation of an investigator-initiated clinical trial.
- While the focus of the Early Clinical Investigator Award is on patient-oriented research, complementary laboratory-based research directly related to the proposed patient-oriented research project may be proposed in the application and is encouraged for therapeutic trials, thereby providing an opportunity to obtain preclinical data and to develop and validate any proposed correlative assays with a laboratory-based collaborator. If correlative studies are proposed, a qualified collaborator who is able and willing to participate in the design and conduct of the correlative studies needed should be identified and, if not already identified as a comentor, provide a letter of intent to collaborate and a biosketch.

Clinical Trial Plan

- Describe the planned investigator-initiated clinical trial protocol that the candidate will lead as the Principal Investigator, including metrics for success, and a timeline to initiation of the trial within the first 2 years of the award.
- The description should include rationale, objectives, end points, correlative studies, and statistical considerations. Trials that incorporate corresponding translational research are strongly encouraged.
- Applicants are advised to pay close attention to careful documentation of the trial's feasibility and inclusion of robust statistical considerations.

9.2.8. Mentor, Comentor (4-page description)

Name a primary mentor who, together with the candidate, is responsible for planning, directing, monitoring, and executing the proposed program. The primary mentor is required to be an experienced clinical investigator. Comentors as appropriate to the goals of the program are encouraged.

Include a statement from the mentor providing (1) information on his/her background as a clinical investigator and previous experience as a mentor, (2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period, (3) a plan for career progression for the candidate to move from the mentored stage of his/her career to independent research investigator status during the project period of the award, and (4) a plan for monitoring the candidate's research, publications, and progress over the course of the award.

Similar information must be provided by any comentor. The mentor and any comentor(s) should clearly describe how they will coordinate mentoring of the candidate.

The primary mentor must agree to provide annual evaluations of the candidate's progress in the annual progress report.

9.2.9. Mentor, Comentor Biographical Sketches (5 pages each)

Biosketches that include current and past funding for the mentor and all comentors must be provided. Biosketches should also include education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 5 pages.

9.2.10. Biographical Sketches of Collaborators (5 pages each)

Applicants may provide up to 2 additional biographical sketches for collaborators or key personnel. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

9.2.11. Timeline (1 page)

Provide an outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. **Note that the progress report at the**

completion of Year 2 of this award must include an investigator-initiated clinical trial protocol and a detailed timeline for implementation.

If the application is approved for funding, this section will be included in the award contract and will be used to monitor progress. Failure to demonstrate robust progress may result in early termination of the grant award. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

9.2.12. Current and Pending Support

State the funding source, duration, and title of all current and pending financial support including any research awards held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

9.2.13. Letters of Recommendation

Provide 2 letters of recommendation from individuals in addition to the mentor and comentor who can detail the candidate's academic accomplishments, potential as a clinical investigator, and ability to make a significant contribution to the field of cancer research.

9.2.14. Research Environment (1 page)

Clearly and concisely describe the research environment available to support the candidate's research program as well as access to clinical facilities and patients, core facilities, didactic programs, and collaborative opportunities.

9.2.15. Collaborator Support and/or Other Certification (2 pages)

Applicants may provide letters of collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 2 pages may be provided.

9.2.16. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

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

9.3. 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:** Headers and footers should not be used (unless they are part of a provided template).

- **Page Numbering: DO NOT** add page numbers in any of the submitted documents. These will be added automatically by the system when the application is concatenated.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

10. APPLICATION REVIEW

10.1. Review Process

All applications will undergo a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. 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 in section 10.3. Applicants will be notified of peer review panel assignments prior to the peer review meeting dates. Peer review panel membership can be found on the CPRIT website. 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 Scientific Review Council based on comparisons with applications from all the peer review panels and programmatic priorities. Applications approved by Scientific Review Council 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.

10.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council 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 Review Council members are non-Texas residents.

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, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of the Department 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. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

10.3. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for development as a clinical investigator. **Also of critical importance is the strength of the institutional commitment to the candidate's career development and the track record of the candidate's mentor(s).**

Review criteria will focus on the overall impression of the candidate and the proposed career development plan, the institution's commitment to the candidate's career development as a clinical investigator, and his or her long-term potential to have an impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated academic excellence? Has the candidate received excellent training as a clinician in a cancer discipline? Does the candidate show exceptional potential for making an impact on cancer research in the future?

Institutional commitment and mentorship plan: Will the candidate have enough time and support to develop as a clinical investigator? Is the mentor(s) and mentorship plan well developed and tailored to guide the candidate to achieve the candidate's career goals?

Relevance of Candidate's career and clinical trials plan: Is the proposed area of focus likely to have a significant impact on reducing the burden of cancer in the near term?

Letters of Recommendation: Do the letters of recommendation detail the candidate's academic and clinical accomplishments, potential for innovation as a clinical investigator, and ability to make a significant contribution to the field of cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources including access to patients to support the candidate's development? Is there evidence of strong institutional support? Will the candidate's administrative/clinical responsibilities be sufficiently limited so that he or she can focus on growing his or her research? Has the institution identified a mentor who will collaborate with the candidate in the design and oversight of a faculty career development plan for the candidate? If correlative studies are proposed, is a qualified collaborator who is able and willing to participate in the design and conduct of the correlative studies needed identified.

11. KEY DATES

RFA

RFA release	August 28, 2024

Application

Online application opens	September 18, 2024, 7 AM central time
Application due	December 10, 2024, 4 PM central time
Application review	March 2025

Award

Award notification	May 2025
Anticipated start date	June 1, 2025

12. 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. Awards made under this RFA are not transferable to another institution. 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 Texas Administrative Code, Title 25, chapters 701 to 703.

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 Texas Administrative Code, Title 25, chapters 701 to 703.

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, Texas Administrative Code, Title 25, chapters 701 to 703.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals outlined in section 9.2.6 and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. **CPRIT's Academic Research Program staff reviews the progress reports, and continuation of funding is contingent upon demonstration of progress and achievement of the goals set forth in** section 9.2.6. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the

termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

13. 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, Texas Administrative Code, Title 25, chapters 701 to 703, for specific requirements regarding the demonstration of available funding.

14. CONTACT INFORMATION

14.1. Helpdesk

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration and online submission of applications as well as page limitations, formatting, and how to upload application components/subsections in the appropriate tabs of CARS. Helpdesk staff cannot answer scientific questions and/or Academic Research Program aspects of an application. Before contacting the Helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

14.2. Scientific and Programmatic Questions

Scientific and programmatic questions should be directed to the CPRIT Director of Academic Research. **Before contacting CPRIT, please refer to the *Instructions for Applicants* document and contact the Helpdesk for any items related to the CARS, page limitations, formatting, etc.**

Email: research@cprit.texas.gov

Website: www.cprit.texas.gov