CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-26.1-IIRACT

Individual Investigator Research Awards for Clinical Trials

Please also refer to the Instructions for Applicants document, which will be posted on January 14, 2025.

Due to the highly competitive nature of this RFA mechanism and available funds for FY26, CPRIT projects that only 10% of submitted applications will be funded

Application Receipt Opening Date: February 18, 2025

Application Receipt Closing Date: May 6, 2025

FY 2026

Fiscal Year Award Period

September 1, 2025-August 31, 2026

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RFA VERSION HISTORY

1/14/25	RFA released
3/26/25	Updated links to Texas Administrative Code

1. BRIEF DESCRIPTION OF RFA

- Supports applications that propose innovative cancer clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Applications must provide documentation that the proposed clinical trial will be ready to commence immediately upon award of the Cancer Prevention and Research Institute of Texas (CPRIT) contract and that the clinical trial goals are feasible within the proposed project timeline.
- Applicants are required to complete a checklist (required template provided in the CPRIT Application Receipt System (CARS) under *Current Funding Opportunities*). **Applicants must provide the full clinical trial protocol at the time of submission.**
- Applicants may request a maximum of $400,000 per year for a period of up to 4 years.
- **Multi-Principal Investigators (MIs)** are allowed under this Request for Applications (RFA). Refer to the Instructions for Applicants (IFA) document for definition and eligibility of MIs.
- See application limitations for **Principal Investigators (PIs)/MIs**, regardless of whether the MI is from the prime institution or a subcontracted institution.
- **Note that CPRIT does not allow the use of the term Co-PI**.
- Minimum level of effort for the PI and/or MIs throughout the project period is required.
- A PI and/or MI may not submit more than **one application** for this RFA (defined as either a new application, resubmission application or competitive *renewal application).
- *Renewal applications are limited to one competitive renewal under this RFA, regardless of the year of the funded parent Individual Investigator Research Awards for Clinical Trials (IIRACT) award.
- The FY26 salary cap is $225,000 per year.

2. ABOUT CPRIT

The State of Texas has established 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; and
- Develop and implement the Texas Cancer Plan.

2.1. 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 in all regions of the state
- Reducing cancer disparities.

The program priorities for academic research adopted by the Oversight Committee include funding projects that address or utilize 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, early detection, or risk assessment approaches and interventions
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer
- Expanding access to innovative clinical trials
- Cancer survivorship research to enhance the health and well-being of cancer survivors and caregivers.

3. RATIONALE

This IIRACT mechanism supports applications that propose innovative cancer clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices. Such clinical trials offer important opportunities to incorporate biomarkers, pharmacokinetic and pharmacodynamic monitoring, and/or imaging studies to provide more precise knowledge about what works, in whom, and in which types of cancer, and to guide subsequent clinical development of a novel cancer therapy.

The research supported by this mechanism is important because current clinical development of novel cancer therapeutics remains slow and expensive with many late-stage failures. Only 5% of cancer therapeutics that enter clinical evaluation will be approved, and the approval process is often measured in decades. There is an urgent need to accelerate and enhance the efficiency of this process by improving the clinical evaluation of novel cancer therapeutics through adoption of modern trial designs that incorporate biomarkers. Such trials will build on advances in basic discovery that have identified the critical targets involved in the hallmarks of cancer and have led to mechanism-based therapeutics. Trials that are designed to determine if predictors of response and efficacy identified in preclinical models also occur in patients have the potential to accelerate therapeutic development and approvals. They also guide the development of diagnostic tests to identify those patients most likely to benefit from these new treatments. Well-conducted early-phase studies will also inform reasons for treatment failure and feed back to preclinical studies designed to overcome barriers to success identified in patients.

4. RESEARCH OBJECTIVES

The goal of the IIRACT is to promote clinical research that will lead to a better understanding of the clinical efficacy of a cancer therapy or diagnostic device. Applications submitted under this mechanism should propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial.

Clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices are all responsive to this RFA.

Applications that propose the development and validation of a biomarker prior to use of that biomarker in a prospective clinical trial are not responsive to this RFA and should be directed to the CPRIT IIRA mechanism RFA R-26.1-IIRA. Applications that propose only correlative or biomarker studies in the context of a clinical trial conducted under other funding mechanisms are not responsive to this RFA.

Early-phase clinical trials of agents or combinations of agents for which there are robust nonclinical data that suggest there may be clinical activity are responsive to the RFA, even if there is no biomarker, as long as the early-phase clinical trial will lead to determining if the activity observed in the laboratory can be replicated in patients.

Additional examples of the types of studies appropriate for the IIRACT include, but are not limited to, phase 1 or small phase 2 trials of new agents, repurposed agents, radiation therapy, surgery, or combinations of interventions where the trial design incorporates biomarker and/or imaging strategies to determine one or more of the following: presence of the drug target, target inhibition, biological pathway inhibition, or pathophysiological alteration by the investigational drug or device. CPRIT recognizes the value of supporting trials sponsored by pharmaceutical companies. In this situation, the applicant should provide documentation from the industry partner as to what is being provided by the industry partner, ie, drug(s) only versus drug and funds for study conduct (may be partial funding) versus drugs and funds for study conduct and funds for correlative or translational studies or other resources.

5. FUNDING INFORMATION

Applicants may request a maximum of $400,000 per year for a period of up to 4 years. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs including diagnostic or interventional procedures associated with participation in a clinical trial and not considered routine patient care, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not

be approved under this funding mechanism. State law limits the amount of indirect costs to no more than 5% of the total award amount.

The budget justification must include a timeline for the clinical trial initiation and accrual targets. Applications must provide documentation that the proposed trial will be ready to commence immediately upon award of the CPRIT contract and the trial goals are feasible within the project timeline. For example, drug access through an industry or CTEP arrangement should be documented. When indicated, an approved investigational new drug application (IND) or investigational device exemption (IDE) for devices from the Food and Drug Administration (FDA) should be cited, or if no IND is yet available for the agent(s), then a pre-IND meeting would have been held with the FDA, and the summary letter from that pre-IND meeting would be included as an attachment (see section 9.2.13).

Please see section 9.2.15 and the IFA for additional information.

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts 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; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Research Program.
- The PI must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and must be a full-time resident of Texas during the time the research that is the subject of the grant is conducted.
- The PI must hold an appointment at the rank of assistant, associate or professor tenure track or tenured (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation. The PI must also have appropriate designated laboratory or clinical space, or other facilities in which to conduct the proposed studies. This award mechanism allows MIs for projects that require a team science approach (see the IFA for guidelines on CPRIT rules for MI awards).
- For applications that include 1 PI, the PI is required to maintain a minimum of 15% level of effort through the duration of the entire award period. For applications that include MIs,

each PI is required to maintain a minimum of 10% effort through the duration of the entire award period.

- A PI may not submit applications to this RFA and to RFA R-26.1-IIRA, RFA R-26.1-IIRACSBC, RFA R-26.1-IIRACCA, RFA R-26.1-IIRAP, or RFA R26.1- IIRAEOC.
- A PI may not submit more than 1 application, either a new, resubmission, or renewal application under this RFA during this funding cycle.
- A PI may be a part of only one application, whether as a single applicant or as an MI on an application, under this RFA and RFA R-26.1-IIRA, RFA R-26.1-IIRACCA, RFA R-26.1-IIRACSBC, RFA R-26.1-IIRAP, or RFA R-26.1-IIRAEOC.
- **An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants.** Recruitment grants and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers MIRA Project MIs equivalent to a PI. For the purpose of calculating the number of active grants, CPRIT will consider the number of active grants at the time of the award contract effective date (for this cycle expected to be December 1, 2025).
- Applications that address prevention and early detection, cancers in children and adolescents, or computational systems biology of cancer should be submitted under the appropriate targeted RFA. As noted in section 4, applications that propose the development and validation of a biomarker prior to use of that biomarker in a prospective clinical trial are not responsive to this RFA and should be directed to the CPRIT Individual Investigator Research Award mechanism RFA R-26.1-IIRA.
- Collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, 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 PI, 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.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, regardless of whether those individuals are slated to 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** and must follow all resubmission guidelines and be eligible for this mechanism under the criteria in section 4. If a previously submitted application does not meet the new criteria for this mechanism outlined in section 4 it must be resubmitted under the IIRA mechanism. **More than 1 resubmission is not permitted.** Applications resubmitted more than once will be administratively withdrawn. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project, a change in the project title that was previously submitted to CPRIT, or omission or modification of an aim does not constitute a new application; the application would be considered a resubmission. This policy is in effect for all applications submitted to date. See section 9.2.6.

8. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA, IIRACCA, IIRACSBC, or IIRAP that is appropriate for the IIRACT mechanism may be submitted under this RFA for a competitive renewal. See section 9.2.7. If an application originally funded as an IIRACT no longer meets the new criteria for this mechanism, it must be resubmitted under another mechanism, eg, the IIRA mechanism. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See section 10.2. Renewal applications are limited to one competitive renewal under this RFA, regardless of the year of the funded parent IIRACT award.

9. RESPONDING TO THIS RFA

9.1. Application Submission Guidelines

Applications must be submitted via 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 PI 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. Applications will be accepted beginning at 7 AM central time on February 18, 2025, and must be submitted by 4 PM central time on May 6, 2025. **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 grant 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 for details. The IFA 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 6 will be administratively withdrawn without review.

9.2.1. Abstract and Significance (5,000 characters)

It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance of the research alone. Therefore, applicants are advised to prepare this section wisely. Based on the Abstract and Significance statement (and the Specific Aims), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from peer review (see section 10.1). Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

Clearly explain the question or problem to be addressed and the approach to its answer or solution. Provide the hypothesis to be tested, the specific aims, and the overall experimental approaches. Indicate whether this proposed clinical research addresses cancers with disparities and/or whether the trial will enroll patients from underserved populations.

Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones or may lead to changes in practice. Indicate whether this research plan represents a new direction for the PI.

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

Provide a layperson's summary of the proposed work. 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 research, early

detections, prevention, 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 (section 10.2) to evaluate the significance and impact of the proposed work during peer review.

9.2.3. Specific Aims and Subaims

Please provide a description of the aims and subaims and milestones to be achieved for each year of the project. At least 1 specific aim and 1 subaim are required. Provide 2 to 3 sentences describing activities to be performed and anticipated milestones. These aims will also be used during the submission and evaluation of progress reports and assessment of project success. Up to 5 specific aims and 5 subaims per specific aim may be entered.

9.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications.

Since a clinical trial is proposed as a component of this application, the timeline must include clearly defined patient accrual milestones.

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.

9.2.5. Specific Aims (1 page)

Please provide a 1-page summary of the aims of the proposal. The Specific Aims page should identify the problem or gap in our current knowledge. It should present a hypothesis and briefly describe the aims, subaims, and approaches. Address the proposal's innovation, novel approaches and significance and impact on the field and cancer research. Please also refer to the template located in *Current Funding Opportunities* for Academic Research in CARS.

9.2.6. Resubmission Summary (2 pages)

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.

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 only editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

9.2.7. Renewal Summary (2 Pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary. Renewal applications are limited to one competitive renewal under this RFA, regardless of the year of the funded parent IIRACT award.

9.2.8. Summary Checklist (1 Page)

Applicants are required to complete a summary checklist. The required template is provided in CARS under *Current Funding Opportunities*.

9.2.9. Research Plan (11 pages)

Background: Provide the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed. Describe the innovation and potential impact of the research.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the

proposed hypothesis are strongly encouraged. This section has been lengthened to allow the applicant to present the statistical considerations used to determine a trial design, accrual milestones, and biomarker validation. Describe the population of eligible patients and plans to enroll unique populations, e.g., underserved populations.

9.2.10. Vertebrate Animals (1 page)

If vertebrate animals will be used, provide a detailed plan of the protocols that will be followed and justification for the number of animals used with reference to biostatistical input for sample selection and evaluation. Certification of approval by the Institutional Animal Care and Use Committee (IACUC) of the proposed animal use will be required before funding can occur.

9.2.11. Human Subjects (2 pages)

For the use of human subjects or human biological samples, provide a detailed plan for recruitment of subjects and/or the acquisition of samples that will meet the time constraints of this award mechanism. Certification of approval of these plans by the institutional review board will be required before funding. If human cells will be purchased for the proposed research, the applicant must include a description of the human cells. If cell lines will be used in the proposed research, the applicant must include a description of the cell lines.

9.2.12. Protocol Documentation

Provide a full protocol of the clinical trial; a PDF copy of the full protocol can be attached. Failure to include the full clinical protocol will result in administrative withdrawal without review of the application.

9.2.13. Investigational New Drug Application (IND)/ Investigational Device Exemption (IDE)

If a clinical trial is proposed that requires an IND or IDE, attach an approved IND or IDE from the FDA to the proposal. If no IND is yet available for the agent(s), then provide a summary letter from a pre-IND meeting held with the FDA. If the drug or device is to be provided through an industry or CTEP mechanism, provide documentation that the drug or device will be available.

9.2.14. Publications/References

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

9.2.15. Budget and Justification

Provide a detailed justification of the budget for the entire proposed period of support, including salaries and fringe benefits, supplies, equipment, costs associated with the conduct of a clinical trial, animal care costs, subject participation costs including diagnostic or interventional procedures associated with participation in a clinical trial and not considered routine patient care, and travel to scientific/technical meetings or collaborating institutions. The PI and related research project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference. Meals are not reimbursable for trips that do not include an overnight stay. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. While there will be 1 budget for the entire project, an individual budget and budget justification for the conduct of a clinical trial must be included. The justification should include the statistical considerations that led to the clinical trial design, accrual milestones, and validation of biomarkers. CPRIT recognizes that industry partners may provide various levels of support, eg, (1) the provision of drug only versus (2) drug and funds for study conduct versus (3) drug, funds for study conduct, and funds for translational studies. The applicant must provide documentation from the industry partner, delineating their contribution to the study, and must provide a strong and clear justification for funds requested from CPRIT for trials of industry-sponsored agents. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level.

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 $10,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Per Texas Grant Management Standards, as of September 1, 2024, for all CPRIT grantees, the minimum threshold for equipment purchases is $10,000. Generally, any purchases up to $9,999 should now be categorized as supplies.

- 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 maximum annual salary (also referred to as direct salary or institutional base salary) that an individual may request under a CPRIT award for FY 2026 is $225,000; CPRIT FY 2026 is from September 1, 2025, through August 31, 2026. 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, patient 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.
- Funds can be used to pay for costs that a cancer clinical trial participant may have associated with their participation in a clinical trial, including (1) transportation, including car mileage, parking, bus fare, taxi or ride hailing fare exclusive of tips, and commercial economy class airfare within the borders of the State of Texas, and (2) lodging.

9.2.16. Biographical Sketches (5 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, any additional MIs (for an MI application), as required by the online application receipt system. Up to **5 additional** biographical sketches for key personnel may be provided, these should be concatenated into a single PDF with a 25-page limit**. Each biographical sketch must not exceed 5 pages**. The NIH biosketch format is appropriate.

9.2.17. Current and Pending Support

Describe the funding source and duration of all current and pending support for 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 and a preliminary brief statement on plan to mitigate potential overlap. At a minimum, current and pending support of the PI and, if applicable, any additional MIs (if an MI application), must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

9.2.18. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

9.2.19. 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 that do not meet the eligibility requirements listed above will be administratively rejected 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 may be submitted as part of the 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. URLs of publications referenced in the application may be included.

  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 must 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 **Page Numbering section** below).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be printed, signed, scanned, and then uploaded in PDF format.

10. APPLICATION REVIEW

10.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications shall undergo a preliminarily evaluation for scientific merit and potential impact by a CPRIT Scientific Peer Review Panel consisting of scientific experts.

The preliminary evaluation is based on a subset of material presented in the application—namely, the Abstract and Significance and the Specific Aims page. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for full peer review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation has concluded. Due to the volume of applications to be reviewed, comments provided by reviewers at the preliminary evaluation stage may be limited.

10.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using 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 10.4. 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 of the peer review panels and programmatic priorities. Applications approved by the 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, chapter 703, sections 703.6 to 703.8.

10.3. Confidentiality of Review

Each stage of the application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, 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 Peer Review Panel members and Scientific Review Council 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 (Texas Administrative Code RULE §703.9)

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 Peer Review Panel 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 Officer, the Chief Product Development Research 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 when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

10.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Peer review committees will evaluate and score each primary criterion and subsequently assign an overall score that reflects a complete assessment of the application. **The overall score will not be an average of the individual criteria scores; 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.**

10.4.1. Primary Criteria

The 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 results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed with potential alternative approaches?

Applicant Investigator: Does the investigator(s) demonstrate the required creativity and expertise to make a significant contribution to the research? Applicants' credentials will be evaluated by the biosketch provided and in a career stage-specific fashion. Have early-career-stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant(s) devoted a sufficient amount 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 applications for CPRIT support.

10.4.2. Secondary Criteria

Secondary criteria contribute to the global overall 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 proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: Is the vertebrate animals and/or human subjects plan adequate and sufficiently detailed?

Budget: Is the budget appropriate for the proposed work?

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

11. KEY DATES

RFA	
RFA release	January 14, 2025
Application	
Online application opens	February 18, 2025, 7 AM central time
Application due	May 6, 2025, 4 PM central time
Application review	May 2025-November 2025
Award	
Award notification	November 2025
Anticipated start date	December 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. 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 and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. 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. A grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the 5% indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding. 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.

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, 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 programmatic questions. Before contacting the Helpdesk, please refer to the *IFA* document, which provides a step-by-step guide on preparing an application and 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 IFA document and contact the Helpdesk for any questions related to CARS, page limitations, formatting, etc.**

Email: research@cprit.texas.gov
Website: www.cprit.texas.gov