

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA R-24.2-CIA

Clinical Investigator Award

Please also refer to the Instructions for Applicants document, which will be posted on September 14, 2023

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: October 17, 2023 **Application Receipt Closing Date:** January 18, 2024

FY 2024

Fiscal Year Award Period September 1, 2023-August 31, 2024

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RFA VERSION HISTORY

09/14/23	RFA release
10/17/23	Modified section 9.2 – Application Components; Added Layperson's Summary (Section 9.2.2) as a required application component.
10/17/23	Modified section 7- Eligibility – Added language indicating that "A minimum
	level of 4 person months (33%) full-time professional effort is required for the PI".
10/17/23	Modified section 7- Eligibility – Modified the following sentence "The PI must
	hold active independent peer-reviewed research support for patient-oriented
	research, or hold other funding for clinical research, e.g., support for
	investigator-initiated clinical trials.
01/16/24	Revised to extend the submission deadline to 4 PM central time on January 18, 2024

1. BRIEF DESCRIPTION OF RFA

- The Clinical Investigator Award (CIA) provides protected time (33%-50% effort) for
 midcareer clinician-scientists with specialty training relevant to the delivery of cancer
 care, including therapeutic intervention, early detection, and prevention to devote more
 time to augment their capabilities in clinical cancer research, particularly investigatorinitiated clinical trials, and to provide mentoring to junior investigators in the conduct of
 clinical research.
- Applicants must hold active independent peer-reviewed research support for patientoriented research, or hold other funding for clinical research, e.g., support for investigator-initiated clinical trials.
- Applicants must have a track record of supervising and mentoring patient-oriented researchers.
- PIs must be within 5 years of their first appointment at the associate professor level or equivalent at an accredited academic institution, research institution, government agency, or private foundation. The PI 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.
- Applicants may request a maximum of \$300,000 per year for up to 5 years.
- Multi-Principal Investigators (PIs) (MIs) are not allowed under this RFA.
- Note that the Cancer Prevention and Research Institute of Texas (CPRIT) does not allow the use of the term Co-PI.
- Minimum effort for the PI throughout the project period is required.

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.
- 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 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 these 2024 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 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

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- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions and population research addressing cancer disparities.
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer
- Expanding access to innovative clinical trials, particularly to regions of the state currently with limited access.

3. RATIONALE

The overall goal of the CPRIT CIA is to contribute to ensuring that a diverse pool of highly trained and accomplished physician-scientists is available to address Texas' and the nation's needs in clinical oncology research. 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 has 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, as well as 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 and maintain a career as a clinical investigator.

There is concern that this pattern of oncology-trained clinicians electing not to 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 with the protected time from clinical responsibilities that is required to develop and conduct investigator-initiated clinical trials.

4. **OBJECTIVES**

The CIA is designed to enable midcareer clinician-scientists with specialty training relevant to delivery of cancer care, including therapeutic intervention, early detection, and prevention to do the following:

- Devote more time to augment their capabilities in clinical cancer research; and
- Provide mentoring to junior clinical investigators in the conduct of clinical research,
 contributing to stabilizing the careers of these individuals so that they can continue to
 conduct clinical research and, ultimately, provide mentorship to others.

PIs are expected to demonstrate a track record in research and the commitment to develop patientdriven hypotheses that can be tested in the clinic with the results, either positive or negative, refining standards of care and informing subsequent clinical research questions.

The CIA is intended to provide protected time to midcareer clinical investigators who exhibit the following:

- Are at the associate professor level or equivalent;
- Have completed specialty training relevant to cancer care, detection, or prevention and are certified by their institution to provide patient care in an oncology-related practice;
- Have an established record of independent peer-reviewed funding in clinical research, a record of supervising and mentoring early-stage researchers, and record of publications;
- Have current active independent peer-reviewed research support for patient-oriented research, or hold other funding for clinical research, e.g., support for investigator-initiated clinical trials;
- Will plan research that involves the conduct of clinical trials involving a therapeutic intervention, early detection, prevention, symptom control, or behavioral interventions; and
- Will maintain existing, or obtain additional, independent peer-reviewed funding as PD/PI
 or MI and assume leadership roles in collaborative clinical research programs.

Note that a CIA recipient who continues to have an independent peer-reviewed clinical research program and to provide mentorship to early-stage investigators can continue to hold this award and contribute to the overall goals of the program if promoted to full professor during the tenure

of the award. Progress in achieving these objectives will be monitored via annual progress reports (see section 12).

The CPRIT CIA will do the following:

- Provide physicians with the opportunity to expand clinical research skills, eg, gaining
 experience in advanced methods and experimental approaches and developing external
 relations with industry and pharmaceutical company partners and clinical research leaders
 at federal agencies.
- Provide an opportunity to establish or expand partnerships with laboratory-based collaborators to design and conduct correlative studies needed to interpret the outcome of an interventional trial.
- Provide the protected time from clinical responsibilities required to develop and conduct investigator-initiated and industry-sponsored clinical trials.
- Increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, who will be able to compete successfully for peer-reviewed grants and become institutional leaders in clinical research and who will mentor the next generation of clinical investigators. CIA recipients will also capitalize on basic discoveries and translate them through the conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.

To accomplish these objectives, the CPRIT CIA will provide awards of up to \$300,000 for up to 5 years to physicians who are within the first 5 years of a faculty appointment as an associate professor to acquire additional skills and experience in clinical research, to develop preliminary data that can be used to prepare applications for future clinical research projects to further both the investigator's career and the CPRIT mission, and to provide mentorship for an early-stage investigator in clinical research. This award may be used for the following:

- To provide salary support to the PI for levels of effort between 4 and 6 months full-time professional effort annually (33%-50%).
- Up to \$75,000 annually may be requested to support didactic study including enrollment in a degree-granting graduate training program course to enhance theoretical and practical skills in design, implementation, and interpretation of data from clinical

investigations or to expand their ongoing clinical trials by including translational studies, such as biomarker studies, correlative studies, or extended data analyses.

Relevance to cancer and to CPRIT's priority areas are important evaluation criteria for CPRIT funding. CPRIT encourages the participation of all groups underrepresented in biomedical research.

5. INSTITUTIONAL COMMITMENT

CPRIT CIAs are intended to provide midcareer clinical faculty with dedicated time for clinical research and to devote more time to augment their capabilities in clinical cancer research and to provide mentoring to new clinical investigators in the conduct of clinical research. The sponsoring institution must provide a letter of commitment to the PI's career goals as a productive, independent investigator and that this commitment to the PI is not contingent upon receiving this award. Additionally, the institution should describe how the PI is an integral part of the institution's research and academic programs. CPRIT recognizes that clinical investigators will need to commit time to direct patient care 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 providing the protected time (4- to 6- person months or 33% to 50% full-time professional effort) required, as well as describe the duties from which the applicant will be relieved and the institutional commitment to, and methods for, enhancing the PI's ability to be a productive independent investigator.

A critical component of the CIA is the identification of a mentee(s) and the design of a mentoring program that is tailored to the goals and prior experience of the institutional pool of mentees. The CIA PI should be a clinical 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 enhancing their capabilities as a clinical investigator.

6. 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 \$1,500,000 (total costs) may be requested. Funding may be used by the clinical investigator for salary and fringe support (salary up to the CPRIT maximum of \$200,000/FTE) for protected time and didactic study including enrollment in a degree-granting graduate program.

Applicants are encouraged to design a scholarly clinical research experience that fits their background and program plan. Funds can be used to provide up to \$75,000 per year for activities that support translational studies. For example, funds may be requested to support (a) research expenses such as supplies, core facility services or outsourced services, eg, for biomarker or correlative assays; (b) travel to research meetings or training; or (c) statistical or analytical services including personnel or computer time. Requests for salary support for mentees 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). PIs and mentee(s) are expected to attend CPRIT's conference. CPRIT funds may be used to reimburse registration, travel, and lodging expenses for the PI and up to 1 mentee to attend the biennial CPRIT conference.

Given the above parameters, CPRIT anticipates that a typical application budget will not exceed \$250,000.

Continuation of funding of this award is contingent upon receipt of an annual progress report that documents achievement of the approved project milestones (see <u>section 9.2.8</u>).

7. ELIGIBILITY

• The applicant must be a Texas-based entity. Any accredited academic institution, research institution, or government agency that provides cancer care and training 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.
- PIs 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 PI.
- At the time of the application, the PI must be within 5 years of their first appointment at the associate professor level or equivalent at an accredited academic institution, research institution, government agency, or private foundation. Assistant professors whose appointment as associate professor will be active by the time of initiation of this award are eligible to apply. The PI 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 PI must have oncology subspecialty training or equivalent and be certified by their
 institution to provide patient care in an oncology-related practice. Individuals with
 specialty training in other areas who are conducting clinical trials relevant to cancer, eg,
 prevention trials, are also eligible. Note: pathologists and radiologists are eligible for this
 award.
- The PI must hold active independent peer-reviewed research support for patient-oriented research, or hold other funding for clinical research, e.g., support for investigator-initiated clinical trials.
- A minimum level of 4 person months (33%) full-time professional effort is required for the PI.
- Multi-PIs are not allowed for this award.
- Individuals who have received a recruitment CPRIT Rising Star Scholar Award or a CPRIT Early Clinical Investigator Award are not eligible for the CIA.
- Individuals who hold an active NCI Clinical Investigator Team Leadership Award are not
 eligible to hold this award concurrently but may hold successive awards. Individuals
 holding an NIH R01 or equivalent award, such as a DOD Congressionally Directed
 Medical Research Programs Peer Reviewed Cancer Research Program Award or a

- CPRIT Individual Investigator Research Award (IIRA), eg, the IIRA Clinical Translation grant, are eligible to apply for the CIA.
- PIs must have identified appropriate junior investigators who are located at the applicant's institution for mentoring and describe this pool (see section 9.2.5).
- 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.

8. RESUBMISSION POLICY

An application previously submitted to CPRIT in response to this RFA but not funded may be resubmitted once following the reissuance of this RFA, based on the eligibility criteria of the initial application, and must follow all resubmission guidelines.

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. PIs 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/Authorized 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 October 17, 2023, and must be submitted by 4 PM central time on January 18, 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. For details, please refer to the *Instructions for Applicants* document that will be available on or about the time that this RFA is posted. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 7 will be administratively withdrawn without review.

9.2.1. Summary of Nomination (2,000 characters)

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

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

Provide a layperson's summary of the proposed work. This section must be completed by the PI. Describe, in simple, nontechnical terms, the overall aims 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 detection, prevention, treatment, or survivorship. 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.

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 <u>and</u>

- the chair of the PI's department. The following information should be included in the letter:
- Describe the PIs selection process and the organization's commitment to the PI's further development as a clinical investigator and mentor.
- State the total award amount and duration requested.
- Document that at the time the CIA contract begins the PI will be appointed at the associate professor level (or equivalent) and will be eligible to provide patient care in a cancer-related discipline at the applicant institution.
- Document the institution's commitment to the PI's career goals as a productive, independent investigator, and that this commitment to the PI is not contingent upon receiving this award. If the individual(s) providing the institutional commitment letter is not the leader of the health care system or individual with authority to approve protected time from clinical service, provide an additional letter of commitment from the appropriate individual confirming the commitment to providing the protected time requested in the application.
- Document the institution's commitment to providing the protected time (4- to 6-person months or 33% to 50% full-time professional effort) required. Breach of this requirement will constitute grounds for discontinuation of the award.
- Provide additional information in support of a PI's research plan to demonstrate how the
 institutional commitment through development of strategic collaborations and leveraging
 the institution's unique strengths will foster the PI's career trajectory.

9.2.4. Specific Aims and Subaims (1,200 Characters per Aim and per Subaims)

List specific aims and subaims for each year of the project. These aims and subaims will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. This section and the following section (9.2.4) must be prepared by the PI.

9.2.5. PI Information and Career Development Plan (12 pages)

PI Background

- Describe the PI's short- and long-term career objectives in patient-oriented research and in mentoring new clinician investigators.
- Provide a summary of the research career of the PI, documenting the clinical and research
 accomplishments and ability of the PI to conduct patient-oriented research and
 commitment to a career in clinical research.
- Describe the PI's clinical and other professional responsibilities/activities in the grantee institution beyond the commitment to clinical research and elsewhere, and describe their relationship to the proposed activities on this award.
- Describe the PI's ability to provide mentoring to new clinician investigators. Provide the number of years of mentoring experience, mentoring role, the number of clinicians mentored, the specialties of individual mentees and the stages in their professional career. Describe the types of research conducted by the individuals mentored and the proportion of mentored individuals currently in academic medicine and/or directly participating in patient-oriented research.
- Provide an explanation of how relief from patient care or administrative responsibilities through protected time provided by this award will contribute to the development or expansion of the PI's clinical research program and increased level of commitment to mentoring early-stage clinical investigators. It is important to convey to the reviewers the rationale for needing protected time to continue a vibrant research program and that this award will permit the PI to spend more time on research and mentoring and less time on administrative and clinical responsibilities for the institution.

Career Goals and Objectives

• Describe the PI's career goals and objectives under this award, including prior experience and current research support. A timeline for accomplishing these goals may be included.

Career Development Plan and Training Activities

- Describe the professional responsibilities/activities including other research projects beyond the minimum effort commitment to the career award. Explain how these responsibilities/activities will help ensure career progression.
- Describe any didactic and research experience(s) designed to develop the necessary knowledge and research skills in scientific areas relevant to the PI's career goals and how

- these skills and experiences will significantly enhance his/her ability to advance his/her research program.
- Demonstrate that the PI has received training or will participate in training covering the legal and ethical issues associated with research on human subjects, as well as other issues relevant to clinical research, eg, FDA regulatory process.

Research Plan

- Describe a sound research plan that is consistent with the PI's level of research development and objectives and his/her career development plan. The research description should demonstrate not only the quality of the PI's research but also the novelty, significance and impact, creativity, and approach, as well as the ability of the PI to carry out the proposed research. Describe how this award will be used to help augment the PI's research skills and/or to develop new directions in clinical research.
- Briefly describe currently funded research (hypotheses and specific aims, background, significance and rationale, preliminary studies, results, and research design) to permit the peer reviewers to evaluate the extent, novelty, and quality of the PI's research activities and opportunities for mentoring.
- This award provides an opportunity for the PI to expand their ongoing clinical trials. Examples include biomarker studies, correlative studies, or extended data analyses. In this event, the description of the studies should include a statement of the hypothesis and specific aims, background, preliminary studies, significance and rationale, and research design and methods. It is not expected that this section will be as detailed as an investigator-initiated research grant; however, sufficient detail should be provided to permit an evaluation of the scientific merit of the research and to showcase the opportunities for mentoring. If correlative assays are proposed, the studies may be outsourced or performed using the services of a core facility. Alternatively, a qualified investigator who is able and willing to participate in the design and conduct of the correlative studies needed may be identified and included as a collaborator. In the *Research Environment* section (section 9.2.11), documentation must be provided that appropriate and adequate resources, both in terms of support and facilities, are available

to the PI to conduct the research, an important component of rationale and justification of the need for protected time.

9.2.6. PI's Plan to Provide Mentoring (4-page description)

- Describe the availability of early-stage investigators for mentoring; their previous training and specialization; plans for recruitment, selection, and supervision; the types of educational and research experiences that will be provided; and the role and activities of the CIA PI in mentoring, including proposed level of effort dedicated to mentoring for the PI.
- If there is an existing clinical research curriculum, for example, through the CTSA or Cancer Center's Clinical Trials Office, describe how the mentoring plan will be integrated with the curriculum. PIs must also describe a plan for supporting the research of their mentees during the period of the career award.
- The PI must provide mentoring for at least 1 junior clinical researcher during this award period. Applications that fail to document the availability of multiple mentees or a high likelihood of mentoring multiple clinical researchers are less likely to be viewed favorably by reviewers.

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

9.2.7. PI Biographical Sketch (5 pages)

A biosketch that includes current and past funding for the CIA PI 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. The NIH biosketch format is appropriate.

9.2.8. Biographical Sketches of Collaborators (5 pages each)

Applicants may provide up to 4 additional biographical sketches for co-mentors, collaborators, or key personnel. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

9.2.9. 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. 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.

9.2.10. 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 PI. If the PI 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.

9.2.10 Institutional/Collaborator Support and/or Other Certification (2 pages)

Applicants may provide letters of institutional support, e.g., documentation of services to be provided by a core facility, confirmation of collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 2 pages may be provided.

9.2.11. Research Environment (1 page)

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

9.2.12. 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:** 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.

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 twothirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, <u>Texas Administrative Code</u>, <u>Title 25</u>, 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, <u>Texas Administrative Code</u>, <u>Title 25</u>, 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 PI, his or her track-record, and his or her potential for further contributions as a clinical investigator. Also of critical importance is the strength of the institutional commitment to the PI's career development.

Review criteria will focus on the overall impression of the PI and the proposed career development plan, the institution's commitment to the PI'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 PI: Has the PI demonstrated academic excellence? Has the PI received excellent training as a clinician in a cancer discipline? Does the PI show exceptional potential for making an impact on cancer research in the future, and mentoring early-stage clinical investigators.

Institutional commitment, career development, and mentorship plan: Will the PI have enough time and support to develop further as a clinical investigator? Is the career development plan well developed and tailored to enable the PI to achieve their career goals? Is the mentorship plan well developed and tailored to guide the mentee to achieve their career goals?

Relevance of PI'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?

Research Environment: Does the institution have the necessary facilities, expertise, and resources including access to patients to support the PI's development? Is there evidence of strong institutional support? Will the PI's administrative/clinical responsibilities be sufficiently limited so that he or she can focus on growing his or her research? Is the pool of early-stage investigators appropriate to ensure the applicant's engagement in productive mentoring? If biomarker or correlative studies are proposed, is a qualified laboratory, or collaborator who is able and willing to participate in the design and conduct of the studies identified.

11. KEY DATES

RFA

RFA release September 14, 2023

Application

Online application opens October 17, 2023, 7 AM central time

Application due January 18, 2024, 4 PM central time

Application review February 2024 to August 2024

Award

Award notification August 2024

Anticipated start date August 31, 2024

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 <u>Texas Administrative Code</u>, <u>Title 25</u>, <u>chapters 701 to 703</u>.

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, <u>Texas Administrative Code</u>, <u>Title 25</u>, <u>chapters 701 to 703</u>.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals outlined in section 9.2.4 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 9.2.3. 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,

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

14. CONTACT INFORMATION

14.1. 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 members 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: <u>Help@CPRITGrants.org</u>

14.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Director for Academic Research.

Tel: 512-305-8491

Email: research@cprit.texas.gov

Website: www.cprit.texas.gov