

### CANCER PREVENTION & RESEARCH Institute of Texas

# INSTRUCTIONS FOR APPLICANTS

Early Clinical Investigator Award RFA R-25.2-ECI

FY 2025

Fiscal Year Award Period September 1, 2024-August 31, 2025

#### **TABLE OF CONTENTS**

1.	INTRODUCTION	. 4
2.	SUMMARY INSTRUCTIONS	. 4
3.	APPLICATION PREPARATION AND SUBMISSION PROCESS	
4.	APPLICATION/AUTHORIZED SIGNING OFFICIAL (ASO)	. 6
5.	GRANTS CONTRACT/OFFICE OF SPONSORED PROJECTS OFFICIAL	
6.	USER REGISTRATION AND/OR LOGIN	
7.	STARTING A NEW APPLICATION	.7
8.	STARTING A RESUBMISSION APPLICATION	. 8
9.	STATUS DISPLAY	
	1. TAB STATUS	
9.	2. APPLICATION STATUS	9
10.	TAB: SUMMARY	10
11.	TAB 1: CONTACTS	11
12.	TAB 2: APPLICATION INFORMATION	12
13.	TAB 3: PROJECT PERSONNEL AND COLLABORATORS	
14.	TAB 4: REQUIRED DOCUMENTS	
15.	TAB 5: BUDGET	
	5.1. BUDGET FOR ALL PROJECT PERSONNEL (USE WEB FORM PROVIDED)	
15	5.2. DETAILED BUDGET FOR YEAR 1	
15	5.3. BUDGET FOR ENTIRE PROPOSED PERIOD OF PERFORMANCE	21
15	5.4. BUDGET JUSTIFICATION	
	5.5. SALARY CAP	
	TAB 6: FINAL REVIEW & SUBMIT	
17.	PROVIDED TEMPLATES	22
18.	FORMATTING INSTRUCTIONS	23
19.	CONTACT INFORMATION	24
19	P.1. Helpdesk	
	9.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	
	ENDIX 1: DESCRIPTION OF RESEARCH AREAS	
APP	ENDIX 2: PROGRAM FOCUS-DEFINITIONS OF CANCER RESEARCH TYPES	27
APP	ENDIX 3: TREC ELIGIBILITY	28

#### **VERSION HISTORY**

8/28/24 Instructions for Applicants document posted

#### 1. INTRODUCTION

The Cancer Prevention & Research Institute of Texas (CPRIT) Application Receipt System (CARS) (https://CPRITGrants.org) provides a means for the research community (ie, nominators, candidates, Principal Investigators [PIs], and Application/Authorized Signing Officials [ASOs]) to respond to CPRIT funding opportunities electronically over the Internet through a secure connection. This document provides instructions and guidance to nominators/ applicants to submit an application in response to CPRIT's Request for Applications (RFA) for an Early Clinical Investigator Award (RFA R-25.2-ECI). Applications may be submitted from September 18, 2024, through December 10, 2024.

#### **IMPORTANT NOTES:**

- An institution may submit only 2 applications under this RFA during this funding cycle.
- Candidates must be physicians within the first 5 years of a faculty appointment at the assistant professor level or equivalent.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.

#### 2. SUMMARY INSTRUCTIONS

- Technical Support: Nominators/applicants and candidates are strongly advised to carefully read this document in its entirety before starting an application. The Helpdesk (section 19.1) is available to answer technical questions and guide nominators/applicants with application submission. This *Instructions* document will be updated as necessary. Revisions will be listed in the *Version History*.
- **Document Format for Uploaded Files:** Use Portable Document Format (PDF) only.
  - Do NOT password protect documents.
  - Do NOT submit documents that are bound together in a single PDF package.
- Font Type/Size: Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Page Format:** Single spacing, 0.75-inch margins in all directions.

- **Templates:** Templates are provided for biographical sketches (biosketches) and current and pending support. NIH-style biographical sketches can be used if desired.
- Submission Process:
  - The candidate prepares the relevant information and documents for the nominator/applicant.
  - The nominator/applicant completes/finalizes all sections in the system and forwards it to the organization's ASO for review and final submission to CPRIT. The ASO is an individual authorized to submit an application for the organization.
  - The application must be submitted by the ASO by December 10, 2024, 4 PM central time.
  - **NOTE**: CARS will be unavailable the third Thursday of each month between 7 PM and 9 PM central time for routine system maintenance.
- Tab Finalization and Reset:
  - Application information saved "as draft" can be edited at a later time.
  - Once application information is "finalized for ASO approval," it can be edited only after an ASO has reset the section to draft mode at the request of the nominator/applicant.
- Application Submission Deadline:
  - The application must be submitted by **December 10, 2024, 4 PM central time.**

#### 3. APPLICATION PREPARATION AND SUBMISSION PROCESS

Nominations for CPRIT's ECI will be submitted on behalf of a specific candidate (PI) 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. <u>All nominations must be submitted via a user account in CARS.</u> Due to the nature of the award, the candidate will prepare and provide information and documents to the nominator/applicant who will then be able to supplement the candidate-provided documents with institutional documents to submit the complete nomination in the system via their user account. As with other CPRIT award mechanisms, the application must be started by an individual (the nominator/applicant) and then forwarded to the institution's ASO for formal submission to CPRIT. A summary of this process is as follows:

- The candidate (PI) prepares the relevant information and documents for the nominator/applicant.
- The nominator/applicant completes/finalizes a series of numbered tabs in CARS for the application.
- Finalized tabs can be reset only by the ASO.
- Once all tabs are finalized, the ASO reviews, approves, and submits the application to CPRIT.

#### 4. APPLICATION/AUTHORIZED SIGNING OFFICIAL (ASO)

The ASO is an individual authorized to submit an application on behalf of an organization. An ASO is required on the application and must be identified by the nominator/applicant. As the organization's representative, the ASO is required to review the tabs finalized by the nominator/applicant and subsequently submit the application. <u>Only the ASO is authorized to officially submit the application to CPRIT.</u> The ASO can reset nominator/applicant-finalized tabs to draft at the request of the nominator/applicant.

#### 5. GRANTS CONTRACT/OFFICE OF SPONSORED PROJECTS OFFICIAL

The Grants Contract/Office of Sponsored Projects Official is the individual who will manage the grant if an award is made. This individual must be identified for the application. The nominator/applicant or the ASO can assign this individual to this role.

#### 6. USER REGISTRATION AND/OR LOGIN

Nominators/applicants begin the application process by registering or logging in to CARS (https://CPRITGrants.org). User accounts for nominators/applicants may be created via the *Register here* link in CARS. All nominator/applicant accounts must select the general role of "I am an Applicant or work for one," a role similar to that of a PI on Academic Research applications. On successful login into the system, nominators/applicants will be presented with the *My Applications* page. All prior applications by that user are listed on this page. After initial registration or after login, all users are encouraged to complete/verify the information under the *My Profile* link on the top left of this screen.

*	Cancer Prevention & Resi Institute of Texas	EARCH	Home Help I FAQ Log O		
Profile My	Applications Bridge My Grants Manage Organizations Curren	nt Funding Opportunities Feedback Review Grants HelpDesk Administrative			
count Informat	on Contact Information Descriptive Information Biosketch				
		Logged in as: Sys	stem Admin [ not System Admin Home > My Profile > Ap		
		My Profile: Account Info	riome > My Profile > Ad		
		My Profile: Account Info			
Your account in	nformation is comprised of basic identification. You may edit this informatio	on at any time.			
	normation is comprised of basic identification. You may edit this information riked with " are required 1 am an Applicant or Work for One	on at any time. CPRIT is collecting your ORCID ID so we can have access to your ORCID profile at the time of applic	ation submission.		
The entries ma Role Salutation *	rked with * are required I am an Applicant or Work for One Ms. ~	CPRIT is collecting your ORCID ID so we can have access to your ORCID profile at the time of applica Clicking on the button below will connect your profile in the Application Receipt System with ORCID.	You will then be able to		
The entries ma Role Salutation * First Name *	rked with * are required I am an Applicant or Work for One	CPRIT is collecting your ORCID ID so we can have access to your ORCID profile at the time of applica- Clicking on the button below will connect your profile in the Application Receipt System with ORCID. sign in to your ORCID account if you already have one; if you do not have an ORCID I and profile, for one. Next, when you click the "Authorize" button, you will be asked to share your Du sing an aut	You will then be able to you will be able to register henticated process. This will		
The entries ma Role Salutation *	rked with * are required I am an Applicant or Work for One Ms. ~	CPRIT is collecting your ORCID ID so we can have access to your ORCID profile at the time of applica- Clicking on the button below will connect your profile in the Application Receipt System with ORCID. sign in to your ORCID account if you already have one: if you do not have an ORCID ID and profile. for one. Next, when you click the "Authorize" button, you will be asked to share your ID using an aut grant permission for CPRIT to securely obtain your ORCID ID and ensure that you are correctly ident	You will then be able to you will be able to register henticated process. This will		
The entries ma Role Salutation * First Name * Middle Initial	rked with * are required I am an Applicant or Work for One Ms System	CPRIT is collecting your ORCID ID so we can have access to your ORCID profile at the time of applica- Clicking on the button below will connect your profile in the Application Receipt System with ORCID. sign in to your ORCID account if you already have one; if you do not have an ORCID I and profile, for one. Next, when you click the "Authorize" button, you will be asked to share your Du sing an aut	You will then be able to you will be able to register henticated process. This will		
The entries ma Role Salutation * First Name * Middle Initial Last Name *	rked with * are required I am an Applicant or Work for One ∭s. → System 	CPRIT is collecting your ORCID ID so we can have access to your ORCID profile at the time of applica- Clicking on the button below will connect your profile in the Application Receipt System with ORCID. sign in to your ORCID account if you already have one: if you do not have an ORCID ID and profile. for one. Next, when you click the "Authorize" button, you will be asked to share your ID using an aut grant permission for CPRIT to securely obtain your ORCID ID and ensure that you are correctly ident	You will then be able to you will be able to register henticated process. This will		
The entries ma Role Salutation * First Name * Middle Initial Last Name * Suffix	rked with * are required I am an Applicant or Work for One Ks.  System System Signam S	CPRIT is collecting your ORCID ID so we can have access to your ORCID profile at the time of applica- Clicking on the button below will connect your profile in the Application Receipt System with ORCID. sign in to your ORCID account if you already have one: if you do not have an ORCID ID and profile. for one. Next, when you click the "Authorize" button, you will be asked to share your ID using an aut grant permission for CPRIT to securely obtain your ORCID ID and ensure that you are correctly ident	You will then be able to you will be able to register henticated process. This will		

#### 7. STARTING A NEW APPLICATION

New applications can be started in 1 of 2 ways:

- My Applications (this is the default page after login) → click Start a New Application → FY 2025 Academic Research Programs → Early Clinical Investigator Award → click New Application, or
- Current Funding Opportunities → click FY 2025 Academic Research Programs → Early Clinical Investigator Award → click Start New Application.

Upon starting a new application, nominators/applicants are required to enter the title of the application (160-character limit; can be edited later) and select the submitter role. Symbols or special characters should NOT be used—these will not be transmitted correctly. Once this step is completed, nominators/applicants will be directed to the summary page.

Nominators/applicants are advised to carefully read the information on the summary page before moving on to the numbered tabs.

- Tab 1 (*Contacts*) and Tab 2 (*Application Information*) **must** be completed/finalized prior to Tab 3 (*Collaborators*).
- Tab 2 (Application Information) **must** be completed/finalized prior to Tab 5 (Budget).

All tabs must be completed/finalized by the nominator/applicant before the ASO can review, approve, and successfully submit the application.

#### 8. STARTING A RESUBMISSION APPLICATION

Resubmission applications may be submitted for previously unfunded ECI applications. A resubmission application can be started from the *My Applications* page by clicking the "Start Resubmission Application" link of a previously not funded application.

Upon starting a resubmission application, applicants may revise the title of the application (prepopulated from the previous submission; 160-character limit) and select the submitter role. Do NOT use symbols or special characters—these will not be transmitted correctly. Once this step is completed, applicants will be directed to the summary page. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission.

**NOTE:** Only the title of the previously submitted application is prepopulated for a resubmission application. All other information, including collaborators, and all required documents, must be submitted again. If a summary statement was prepared for the previous application, it will be automatically uploaded as part of the resubmission application (see <u>section 14</u>: Tab 4, *Required Documents*). If a summary statement was not prepared, no document will be uploaded.

Applicants are advised to carefully read the information on the summary page before moving on to the numbered tabs. All tabs must be successfully completed/finalized by the applicant before the ASO can review, approve, and successfully submit the application.

- Tab 1 (*Contacts*) **must** be completed/finalized prior to Tab 3 (*Project Personnel and Collaborators*).
- Tab 2 (Application Information) must be completed/finalized prior to Tab 5 (Budget).

#### 9. STATUS DISPLAY

#### 9.1. Tab Status

The status of each tab is displayed under the row of numbered tabs. The figure below is an example of the status of Tab 1.

My Applications: Contacts				
Summary 1 Contacts 2 Application 3 Perso Information & Collabo Application ID: XXXXXXXX				
Status	Status Definition			
DRAFT	The tab is being prepared by the nominator/applicant.			
PENDING ASO APPROVAL	The tab has been finalized by the nominator/applicant. When all tabs are finalized and reflect this status, the ASO will receive email notification stating that the application can be reviewed/submitted. The nominator/applicant is included on this notification.			
ASO APPROVED AND SUBMITTED	The ASO has reviewed, approved, and submitted the application to CPRIT. Once the application has been submitted by the ASO, the nominator/applicant is notified via email.			

#### 9.2. Application Status

The status displayed under the row of numbered tabs on the *Summary* tab indicates the status of the application (as indicated in the figure above).

#### **10. TAB: SUMMARY**

The status of each tab is also displayed on this page. Status definitions are described below.

My Applications: Summary					
Summary	1 Contacts 2 Application Information	3 Personnel & Collaborators Documents	5 Budget	6 Final Review & Submit	
Summary					
Application ID: XXX	XXXXX		Phase: Full App	lication	Statu CDRAFT
Application Title: screen shot Program: FY 2014 Research Programs Award Type: Individual Investigator Research Awards					
	format requirements. Applications that ements found in the <u>Request for Applic</u>		reviewers' determina	ion of readability may result in rejection of your application. Please	
Full Application Dead	line: February 3, 2014 by 3:00 PM CT	(check current official time)			
This application is in progress and is not ready for ASO approval. Each section outlined below must be completed, finalized, and approved by the ASO at your institution prior to the submission deadline. When all sections have been completed and set to "PENDING ASO APPROVAL", the Application Signing Official will need to approve the application submission in order for it to be forwarded for review. The table below shows the status of each section in the submission process as of December 20, 2013 5:12 PM CT.					
Section #	Application Section			Status	
1	Contacts			draft	
2	Application Information			draft	
3	Project Personnel and Colla	aborators		draft	
4	Required Documents			draft	
5	Budget			draft	
6	Final Review and Submit			NOT APPROVED	

Section	Status	Status Definition	
1-5	Draft	The tab is being prepared by the applicant.	
1-5	Pending ASO Approval	The tab has been finalized by the applicant. When all tabs are finalized and reflect this status, the ASO will receive email notification stating that the application can be reviewed/submitted. The applicant is included on this notification. Only the ASO can revert a tab with this status back to draft.	
6	Not Approved	The application has not been approved/submitted by the ASO.	
6 Pending		All tabs have been finalized by the applicant and reflect the status "PENDING ASO APPROVAL." At this point, the application is awaiting ASO approval and subsequent submission.	
All Tabs	ASO Approved and Submitted	The ASO has reviewed, approved, and submitted the application to CPRIT. Once the application has been submitted by the ASO, the PI is notified via email.	

**NOTE:** As stated in the preceding section, the status displayed under the row of numbered tabs on this page indicates the status of the entire application.

#### 11. TAB 1: CONTACTS

- Nominator/Applicant: Verify information for the nominator/applicant; update as necessary.
- Alternate Submitter (Optional): An alternate submitter may be designated on the application by the nominator/applicant. Follow the search guidelines below.
- Application Signing Official (Required): An ASO <u>must</u> be listed in order to complete/finalize this tab. To designate the ASO, do the following:
  - Click the Search for Application Signing Official button.
  - Enter information, and click the *Search Contacts* button.
  - If the individual is listed on the subsequent search results page, that individual may be added to the application via the *Add Contact* link.
  - If the individual is not listed, different search criteria may be used (for example, using the last name only, spelling variations, etc). Alternatively, the individual may be invited to register in CARS and be part of the application by clicking the *Send them an invitation* link. On the subsequent page, complete the fields, and click the *Send Invitation* button. When this individual joins the application as the ASO, his/her information will be listed in the appropriate section of the tab.
  - Change or remove an individual by clicking the appropriate button.
- Alternate Application Signing Official (Optional): This individual can be assigned only by the ASO. Follow the search guidelines above.
- Grants Contract/Office of Sponsored Projects Official (Required): A Grants
  Contract/Office of Sponsored Projects Official <u>must</u> be listed in order to
  complete/finalize this tab. This individual can be assigned by the nominator/applicant or
  the ASO. Follow the search guidelines above.

When all information is entered, click the *Finalize Contacts Section* button. Note that this tab cannot be finalized until the 3 required fields of this section, namely, "Nominator/Applicant," "Application Signing Official," and "Grants Contract/Office of Sponsored Projects Official" have been completed. Nominator/applicant information is entered automatically; an ASO must be identified and added by the nominator/applicant. The Grants Contract/Office of Sponsored Projects Official may be identified and added by the nominator/applicant.

#### **12. TAB 2: APPLICATION INFORMATION**

#### • Application Identification

- **Award Mechanism:** Verify the listed award mechanism. Note that the award mechanism cannot be changed here.
- Application Type: Verify application type (drop list defaults to New Application or Resubmission, as applicable).
- Application Title: The application title is stated. Edit if necessary.
- Category of Research/Project to be Supported: Applications that support research/projects directed toward childhood and adolescent cancer must select "Yes." If "Yes" is selected, description text is displayed. Edit as necessary.
- **Texas Regional Excellence in Cancer (TREC) Eligibility:** Select the appropriate option based on your institution's eligibility as a TREC institution (see <u>appendix 3</u>).
- Project Information
  - Contract Start Date (mm/dd/yyyy): The contract start date of 6/1/2025 is prepopulated.
  - **Proposed End Date (mm/dd/yyyy):** Enter the proposed end date of the project. The maximum duration is 5 years (60 months) for ECI applications.
- Application Classification
  - **Research Area:** Select the research area that best describes the proposed work. Please refer to the <u>appendix 1</u> for a detailed description of each research area.
  - **Program Focus:** Select the focus of the proposed work. Please refer to <u>appendix 2</u> for the definitions of cancer research types.
  - Cancer Focus: Select the most relevant cancer focus addressed, up to a <u>maximum of</u>
     <u>3</u>. If the focus of the project is not on specific cancer site(s), select All Cancers. The selection of cancer focus in this section assists CPRIT with reporting on cancer research that is being performed.
  - PI Identification: Provide information for the PI (Candidate): name, title, degree(s), gender, race and ethnicity (optional), institution, contact information including telephone number and email address, and expertise.
- Vertebrate Animals: Indicate whether vertebrate animals will be used.

- **Biologic/Anatomic Substances:** Indicate whether cadavers will be used. In addition, specify the use of human anatomical substances. If human anatomical substances will be used, specify if the substances are traceable to specific donors. Also, select applicable safety provisions.
- Human Subjects: Indicate whether human subjects will be used. Specify the gender, age, and ethnicity of the study population. Specify the method of data collection. Provide the general demographic focus. Select the type of clinical trial, if applicable.
- State Legislative Districts
  - **State Senate District:** Enter the State Senate District of your (nominator/applicant) institution. Use the link provided to find this information using the nominator's/applicant's institutional address.
  - State House District: Enter the State Senate District of your (nominator/applicant) institution. Use the link provided to find this information using the nominator's/applicant's institutional address.
- Cancellation of Applications/Awards by Granting Organization (in past 5 years)
  - Select whether the nominator/applicant is currently eligible to receive federal grant funds. If "No" is selected, provide a reason.
  - Select whether the nominator/applicant had an application or award terminated for cause within the last 5 years. If yes, then select the category of Application or Award. Select the Granting Organization. Enter the Award Title, Award Number, Award Amount, and the Reason for Cancellation. Click the *Add Application/Award* link to add additional applications or awards.
- Donations
  - Select whether the grant nominator/applicant or any individual listed on the application has made a donation, gift, or grant to CPRIT, the CPRIT Foundation, the Texas Cancer Coalition, or any nonprofit organization/entity established to benefit CPRIT.
  - If yes, then enter the name of the donor, entity name, donation amount, and date of donation. Click the *Add Donation* link to add additional donations.

- CPRIT Priorities Addressed (from Statute or Texas Cancer Plan)
  - Choose the CPRIT priority addressed in the application. More than 1 priority may be selected.

Review the instructions, and click the appropriate button (*Save Application Information as Draft* or *Finalize Application Information for ASO Approval*) to save entered application information.

**NOTE:** Application information saved "as draft" can be edited at a later time. Application information "finalized for ASO approval" can be edited only after the ASO has reset the application to draft mode at the request of the nominator/applicant.

#### **13. TAB 3: PROJECT PERSONNEL AND COLLABORATORS**

- Investigators and Submitters: Ensure that the nominator/applicant and the candidate/PI are listed.
- Mentor and Comentors: Enter information for the mentor and all comentors (select the appropriate *Role for Application* from the drop list). Click the Save as Draft button to save additions
- **Collaborators:** Enter information for all collaborators (select the appropriate *Role for Application* from the drop list). Click the *Save as Draft* button to save additions. Review the list to ensure that all entered collaborators have been successfully added.
- Note: We recognize that project personnel might not have been identified at this point, so you are not required to list any in this section.

When all information is entered, click the *Finalize Project Personnel and Collaborators* button. Note that this tab can be finalized only after Tab 1 (*Contacts*) has been finalized.

#### 14. TAB 4: REQUIRED DOCUMENTS

**NOTE:** All documents must be uploaded in PDF format only. The system will not allow upload of documents in other formats or of documents that exceed the page limits specified in the individual RFAs. Do NOT password protect documents. Do NOT submit documents that are bound together in a single PDF package.

- Application Abstracts: Summary of Nomination and Layperson's Summary: Enter a summary of the nomination in the designated text box (2,000 characters). Enter a nontechnical layperson's summary of the proposed research in the designated textbox (2,000 characters). Character limits include letters, spaces, and punctuations. Do NOT use symbols or special characters (eg, Greek letters)—these will not be transmitted correctly. Save the entered information by clicking the *Save Application Abstracts as Draft* button. Information must be saved before any documents are uploaded below or the Summary of Nomination will be lost when the upload refreshes the web page.
- Specific Aims and Sub Aims: Please enter your specific aims and sub aims as plain text (1,200 characters per specific aim and per subaim). Specific aims and sub aims will be reviewed during the evaluation of annual progress reports. HTML formatting, tables, charts, and diagrams are not supported. Specific aims and sub aims may be saved as a DRAFT at any time by clicking the Specific Aims and Sub Aims as Draft button. Any unsaved specific aims and sub aims will be lost.
  - At least 1 specific aim and 1 sub aim are required, and at least 1 sub aim is required per specific aim. Up to 5 specific aims and 5 sub aims per specific aim may be entered.
  - Click the Add Sub Aim link to add an additional sub aims to a specific aim.
  - Click the Add Specific Aim link to add additional specific aims.
- Institutional Commitment (3 pages): The institutional commitment should be clearly documented in the application in the form of a letter signed by the nominator/applicant institution's president, provost, or appropriate dean and the chair of the candidate's department. Please refer to the RFA for details on required information regarding institutional support this letter must include.
- **Resubmission Summary (1 page):** Upload the Resubmission Summary PDF document. This option is available for resubmission applications only.
- Curriculum Vitae (CV): Provide a complete CV and list of publications for the candidate/PI. <u>This document must be prepared by the candidate/PI.</u>
- Candidate Information and Career Development Plan (10 pages): Upload the Candidate/PI Information and Career Development Plan. Please include the following

sections: Candidate Background, Career Development Plan, Research Plan, Clinical Trial Plan (see RFA for details and further requirements).

- Mentor, Comentor (4-page description): Upload the mentor and comentor information and mentoring plan (*see RFA for details and requirements*).
- **Biographical Sketches of the Mentor and Comentor:** Upload the PDF biosketches for the mentor and any comentors (a template is posted under the Summary tab, but NIH biosketches may be used). Biosketches must not exceed 5 pages for each individual. If several biosketches are being provided, these must be combined into a single file and submitted as a single PDF document (ie, a 10-page document consisting of two 5-page biosketches).
- Biographical Sketches of 2 Additional Key Personnel (up to 10 pages): If desired, up to 2 additional biosketches for collaborators, or key personnel may be provided. (A template is posted under the *Summary* tab. An NIH biosketch may be used.) <u>Biosketches must not exceed 5 pages for each individual.</u> If 4 biosketches are being provided, these must be combined into a single file and submitted as a single PDF document (ie, a 20-page document consisting of four 5-page biosketches).
- Timeline (1 page): Upload a PDF timeline that provides a general outline of the major outcomes to be tracked during this award. The timeline must match the aims and subaims and the duration requested for the award. Timelines will be reviewed during the evaluation of annual progress reports. A sample timeline can be found under <u>Current</u> <u>Funding Opportunities</u> for Academic Research in CARS. <u>The timeline must be</u> prepared by the candidate/PI.
- Current and Pending Support: Upload the PIs current and pending support (use the template posted under the Summary tab). Refer to the sample current and pending support document located in <u>Current Funding Opportunities</u> for Academic Research in CARS. <u>This document must be prepared by the candidate/PI.</u>
- Letters of Recommendation: <u>Upload 2 letters of recommendation</u> from individuals (<u>other than the mentor or comentors</u>) who are in a position to detail the candidate's academic accomplishments, potential as a clinical investigator, and ability to make a significant contribution to the field of cancer research. These must be combined into a single file and submitted as a single PDF document.

- **Research Environment (1 page):** Upload a PDF document that briefly describes the research environment available to support the candidate's research program, including core facilities, didactic programs, and collaborative opportunities.
- Collaborator Support and/or Other Certification (up to 2 pages): If applicable/desired, upload letters of collaborator support and other certification documents. Multiple letters/files must be combined and submitted as a single PDF document. A maximum of 2 letters may be present on a page. Applicants must NOT submit "appendix material," such as publications, figures, and/or data.
- **Budget Justification:** Upload the Budget Justification PDF document. Provide a <u>brief</u> <u>and concise</u> justification of the budget for the entire proposed period of support for all charge categories: personnel (salaries and fringe benefits), travel, equipment, supplies, consultant charges, contractual (subaward/consortium) charges, research-related subject charges, other expenses (including animal care charges), and indirect charges. <u>Each</u> <u>subaward must itemize project charges for all charge categories (see also section 15.4)</u>.
- Summary Statement of Previous Application: (Applicable for Resubmissions only.) If a summary statement was prepared for the previous application, it will be automatically uploaded as part of a resubmission application. If a summary statement was not prepared, no document is uploaded.

When all information is entered, click the Finalize Required Documents button.

#### **15. TAB 5: BUDGET**

## This tab should include only the amount requested from CPRIT; do NOT include the amount of the matching funds.

The Budget section is composed of 4 subtabs:

- 1. Budget for All Project Personnel
- 2. Detailed Budget for Year 1
- 3. Budget for Entire Proposed Period of Performance
- 4. Budget Justification

All 4 subtabs must be completed to finalize this section. A detailed budget for the first year of the project is required. For the ECI, nominators/applicants may request up to \$1,000,000 over 5 years, inclusive of both direct and indirect charges.

**NOTE:** Some or all of the following buttons appear on each subtab:

**Previous** = Move to the previous subtab

**Next** = Move to the next subtab

Save Budget as Draft = Save entered information

#### Finalize Budget for ASO Approval = Finalize section

The *Previous* and *Next* buttons allow the user to move between subtabs while retaining entered information for as long as the user is on the *Budget* tab. Information entered on any subtab is NOT saved until the *Save Budget as Draft* button is clicked. Moving to another tab without saving will result in loss of any unsaved changes.

Expenses in the proposed budget must be categorized as personnel, fringe benefits, travel, equipment, supplies, contractual, other, and indirect costs. Information on the expenses associated with these budget categories and allowable costs can be found in chapters 9 and 10 of the <u>CPRIT Policies and Procedures Guide</u>. The guide's expense classifications in each budget category carry over to the quarterly financial status report that must completed for every funded project and approved by CPRIT. If for any reason an expense is not categorized correctly in the budget of an application that becomes an approved project, that expense will have to be recategorized to conform to CPRIT's requirements and be approved in a quarterly financial status report.

#### 15.1. Budget for All Project Personnel (use web form provided)

Complete the requested information.

**First Name** and **Last Name**: The candidate/PI's name is prepopulated. Enter names of other individuals, as necessary. Additional rows will autoappear once text is entered into the existing last row.

**Role on Project:** The candidate/PI role is prepopulated. Enter roles of other individuals, as necessary.

**Type of Appointment (Months):** For each individual listed, enter his or her appointment type (eg, 6-month, 9-month, 12-month appointment).

**Annual Base Salary:** For each individual listed, enter his or her institutional base salary. The salary cap for CPRIT awards for FY 2025 (September 1, 2024, through August 31, 2025) is \$225,000; see (section 15.5) Salary Cap.

Effort on Project: For each individual listed, enter his or her percent effort on the project.

**Salary Requested:** After entering the information in these categories, click "Calc" to autocalculate the requested salary.

**Fringe Benefits:** For each individual listed, his or her institutional fringe benefits must be calculated based on direct *Salary Requested*. Fringe benefits may not exceed 35% of the salary requested (a warning will be displayed).

#### 15.2. Detailed Budget for Year 1

Provide the information requested for other direct charges in the first year of the project.

**Travel:** Candidates are expected to attend CPRIT's biennial conference. CPRIT funds may be used to reimburse registration, travel, and lodging expenses for this conference. CPRIT cannot support patient-related travel charges. International travel requires approval prior to the travel occurrence through either the application or the submission of a request after a project is funded.

**Equipment (400-character limit):** Requests for equipment are not appropriate for this award mechanism except in exceptional circumstances that must be very well justified.

**Construction and Renovation:** Requests for construction and renovation are not appropriate for this funding mechanism.

**Supplies (800-character limit):** Itemize costs for research materials, consumable office supplies, and tangible equipment with a cost under \$5,000.

**Contractual (Subaward/Services Contracts)** (400-character limit): Itemize each subaward, consulting service contract, and service contract directly related to the project such as those for contract research organizations or other specialized services. For the purposes of the budget, these are all considered subcontracts. If a project personnel is being paid through a subcontract award, enter a \$0 amount in the Annual Base Salary field and the Salary Requested field and

enter their salary information here. Provide direct contract costs only. Any indirect costs charged on a subcontract must be categorized as an *Indirect Cost* and are calculated in the overall 5% indirect cost limitation. Each subcontract must be itemized in the *Budget Justification* subtab by providing project charges for personnel, travel, equipment, supplies, and other expenses.

**Other (800-character limit):** Itemize other project-associated expenses such as the organization's costs for the participation of human subjects in clinicals trials or animal care charges for animal studies that will not be paid through a contractual arrangement. Funds can be used to pay for any patient care costs outlined in the RFA. To encourage participation in a clinical trial, certain patient costs to participate in a trial such as transportation and lodging are allowable reimbursements based on actual receipts from the patient. (Please see <u>T.A.C. 703.26(f)</u> for more information.) In addition, an organization may provide a nominal incentive to a patient for clinical trial participation. The maximum dollar value allowed for an incentive per person, per activity or session is \$25.00. CPRIT does not fund cash incentives.

**Indirect Costs:** Texas state law limits the amount of award funds that may be spent on indirect costs to no more than 5% of the total award amount (or 5.263% of the direct costs).

<u>Total Indirect Charges for Year 1 (line D) should not exceed 5% of the Total Charges for Year 1 (line E).</u> As an example, for a total award of \$100,000, indirect charges may not exceed \$5,000; direct charges would be \$95,000.

Calculate as follows: Total Indirect Charges = (Total Direct Charges/0.95) - Total Direct Charges.

**Note on Subaward Contracts:** Subawards may recover up to the maximum of 5% in indirect charges of the total requested subaward amount. However, any indirect charges recovered in a subaward count toward the overall 5% indirect cost limitation of the funded award. Therefore, the primary institution completing the application must ensure that all indirect costs are calculated correctly in the total amount requested. If a project is funded, the primary institution receiving the award must manage the subaward contract costs including the allowable indirect costs.

#### 15.3. Budget for Entire Proposed Period of Performance

Amounts for *Budget Year 1* will be autopopulated based on the information provided on the previous subtabs, namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*. For each additional year of support requested, enter the budget requested for personnel charges and other applicable direct charges. Fringe benefits may not exceed 35% of the salary (a warning will be displayed). Adjustments of up to a 3% annual increase for salary and other categories are permitted for additional years. A 3% salary increase for each year after Year 1 is permitted up to the cap of \$225,000. The salary cap (section 15.5) may be revised every year at CPRIT's discretion.

Enter the indirect charges for each additional year of support requested. *Total Indirect Charges* (line D) should not exceed 5% of the total requested award amount for that year (sum of lines C and D).

#### 15.4. Budget Justification

Provide a <u>brief and concise</u> justification of the budget for the entire proposed period of support for all budget categories: Personnel (salaries and fringe benefits), travel, equipment, supplies, contractual charges, other expenses, and indirect charges. <u>Each subaward must itemize project</u> <u>charges for all budget categories.</u>

If you uploaded this document under Tab 4 (*Required Documents*) (see <u>section 14</u>) you can click on the link directing you to your uploaded file. If you have not uploaded this document yet, please click on the link that will direct you to Tab 4 (*Required Documents*) where you can upload this file (see <u>section 14</u>).

#### 15.5. Salary Cap

The salary cap for CPRIT awards in FY 2025 (September 1, 2024, through August 31, 2025) is \$225,000. Thus, the maximum direct salary support an individual can request is up to \$225,000 of his or her institutional salary based on effort on a project. Note: Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs (See RFA for details).

The following table outlines the salary cap guidelines; note that the maximum salary for levels of effort below 100% is proportionate to the allowable direct salary (see the third line in the table as

an example). Institutional fringe benefits should be calculated based on the direct salary support requested.

Base institutional salary (full-time calendar appointment)	Effort on project	Maximum direct salary support that would be requested by the nominator/applicants
Less than \$225,000	1%-100%	Up to base salary
More than \$225,000 (eg, \$300,000)	100%	\$225,000
More than \$225,000 (eg, \$300,000)	50%	\$112,500

#### 16. TAB 6: FINAL REVIEW & SUBMIT

When Tabs 1 through 4 have been completed and finalized by the nominator/applicants, the status of the application is set to "PENDING ASO APPROVAL." The ASO will then receive email notification to review, approve, and submit the application to CPRIT. **Only the ASO is authorized to officially submit the application.** The ASO must log in to the system and click the appropriate application ID number listed under his/her *My Applications* page. To submit the application, the ASO must enter his/her password and click the *Approve and Submit Application* button. The ASO will then be asked to click the *Continue* button to submit the application. After the application has been submitted, the status of the application on the *My Applications* page (and also on all tabs of that application) will be "ASO APPROVED AND SUBMITTED." The ASO at the nominator's/applicant's institution must submit the application by the submission deadline: **December 10, 2024, 4 PM central time.** 

#### **17. PROVIDED TEMPLATES**

It is <u>required</u> that applicants use the provided template to prepare and submit the following documents.

• <u>Current and Pending Support</u> (.doc, .PDF)

A template is provided for the biographical sketch. An NIH biographical sketch may be used if desired. A sample and template is also provided for the Timeline <u>here</u>.

Templates are posted under the Summary tab and are available in .doc and .PDF format.

#### **18. FORMATTING INSTRUCTIONS**

All sections of the application should be written in clear and legible text and must follow the guidelines described below. Nominators/applicants and candidates are advised to use font sizes, font faces, line spacing, page sizes, and page margins that permit easy readability of the application text. Every attempt should be made to keep files sizes to a minimum (see *Scanning Resolution* below). Applications that do not meet these guidelines are subject to administrative withdrawal.

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. Candidates 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:** Nominators/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, PT, Doe, J, White, JM, et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135:45-67.

• Internet URLs: The nominator/candidate are encouraged to provide the URLs of publications referenced in the application; however, URLs directing reviewers to

websites containing additional information about the proposed research should not be included.

- Headers and Footers: Headers and footers <u>should not be used</u> (unless they are part of a provided template).
- **Page Numbering:** <u>DO NOT add page numbers in any of the submitted documents.</u> These will be added automatically by the system when the application is concatenated.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

#### **19. CONTACT INFORMATION**

#### 19.1. Helpdesk

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration and online submission of applications as well as page limitations, formatting, and how to upload application components/subsections in the appropriate tabs of CARS. Helpdesk staff cannot answer scientific questions and/or Academic Research Program aspects of an application.

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

#### 19.2. Scientific and Programmatic Questions

Scientific and programmatic questions should be directed to the CPRIT Director of Academic Research. Before contacting CPRIT, please refer to this document and the corresponding RFA document carefully and contact the Helpdesk for any items related to the Application Receipt System (CARS), page limitations, formatting, etc.

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

#### **Appendix 1: Description of Research Areas**

In <u>Tab 2</u> (Application Information/Application Classification), the nominator/applicant is required to select a research area that best describes the proposed work. Descriptions of research areas are as follows:

- **Cancer biology:** Research on the biology of how cancer starts and progresses as well as normal biology relevant to these processes. Examples include oncogenes and suppressor genes, epigenetics, DNA repair, growth factors, signaling pathways, cancer immunology, microenvironment, and tumor progression and metastasis.
- Cancer control, survivorship, and outcomes research: Research in this category covers a broad range of areas, including patient care and pain management, cancer surveillance, cancer disparities research, quality of life for patients with cancer and their families, identification and reduction of late effects of cancer treatment, education and communications that reduce cancer risk, health services research, and attitudes and belief systems that affect cancer control.
- Childhood and adolescent cancer
- Computational biology and analytic methods
- Early detection, diagnosis, and prognosis: Identification and testing of cancer markers and imaging methods detecting and/or diagnosing cancer as well as predicting the outcome or chance of recurrence. Examples include discovery of markers and/or technologies for use in cancer detection and diagnosis and/or prognosis, animal trials and clinical human trials, tumor response to therapy, risk assessment, screening methods, informatics and informatics networks, and biostatistics.
- Etiology: Research on the causes of cancer—genetic, environmental, and lifestyle factors and their interactions. Examples include environmental chemicals, hormone-disrupting agents, gene-environment interactions, microbial agents, radiation exposure, and genetic polymorphisms that affect carcinogen metabolism.
- **Prevention:** Identification of interventions that reduce cancer risk. Examples include chemoprevention, vaccines to prevent cancer, behavioral modifications that reduce cancer risk, studies on energy balance and dietary factors associated with cancer risk, and identification of cancer risk factors.

- Scientific model systems: Development of new animal models, cell culture systems, computer simulations, and their application to other studies across the spectrum of cancer research. Examples include mathematical modeling of cancer processes, development of diverse animal models, including transgenic mice, zebra fish, *Drosophila*, etc, and development of organ and tissue model systems.
- **Treatment:** Identification, development, and testing of treatments for cancer. Examples include drug development, immunotherapy, personalized cancer therapy, methods of drug delivery, antiangiogenic therapy, clinical trials, and treatments to prevent recurrence.

#### **Appendix 2: Program Focus-Definitions of Cancer Research Types**

In <u>Tab 2</u> (Application Information/Application Classification), the nominator/applicant is required to select a program focus that best describes the proposed cancer research type. Descriptions of cancer research types are as follows\*:

- **Basic Research** results in the acquisition of new knowledge and elucidates fundamental mechanisms in biology.
- **Translational Research** involves the application of discoveries from basic research to practical problems associated with cancer as well as research on how to improve best practices in the community.
- **Clinical Research** involves studies with human subjects and includes patient-oriented research on mechanisms of disease, therapy, and development of new technologies as well as epidemiologic and behavioral studies and outcomes and health services research.

\*Taken from Rubio et al, Defining Translational Research: Implications for Training, *Academic Medicine*. 2010; 85:470-475.

#### **Appendix 3: TREC ELIGIBILITY**

In <u>Tab 2</u> (*Application Information/Application Classification*), the applicant is able to select whether their institution is designated as a TREC-eligible institution.

#### **TREC-Eligible Institutions are as follows:**

- Baylor University
- Texas A&M University
- Texas Tech University
- Texas Tech University Health Sciences Center
- Texas Tech University Health Sciences Center at El Paso
- The University of Texas at El Paso
- The University of Texas Health Science Center at Tyler
- The University of Texas Rio Grande Valley