

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

INSTRUCTIONS FOR APPLICANTS

Individual Investigator Research Awards RFA R-25.1-IIRA

Individual Investigator Research Awards for Prevention and Early Detection RFA R-25.1-IIRAP

> Individual Investigator Research Awards for Cancer in Children and Adolescents RFA R-25.1-IIRACCA

> Individual Investigator Research Awards for Clinical Trials RFA R-25.1-IIRACT

> Individual Investigator Research Awards for Computational Systems Biology of Cancer RFA R-25.1-IIRACSBC

> Individual Investigator Research Awards for Early-Onset Cancers RFA R-25.1-IIRA-EOC

FY 2025

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

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VERSION HISTORY

02/22/24 IFA 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 (i.e., 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 applicants to submit an application in response to CPRIT's Request for Applications (RFA) for Individual Investigator Research Awards (RFA R-25.1-IIRA), Individual Investigator Research Awards for Prevention and Early Detection (RFA R-25.1-IIRAP), Individual Investigator Research Awards for Cancer in Children and Adolescents (RFA R-25.1-IIRACCA), Individual Investigator Research Awards for Computational Systems Biology of Cancer (RFA R-25.1-IIRACSBC), and Individual Investigator Research Awards for Early-Onset Cancers (RFA R-25.1-IIRA-EOC). Applications may be submitted from March 19, 2024, through June 11, 2024.

2. SUMMARY INSTRUCTIONS

- Technical Support: Applicants are strongly advised to carefully read this document in its entirety before starting an application. The CPRIT Helpdesk (section 21.1) is available to answer technical questions and guide applicants with application submission. This *Instructions* document will be updated as necessary. Revisions will be listed in the *Revision 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 applicant completes/finalizes all sections 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 applicant and the ASO will each need to create user accounts in CARS. These are 2 different roles, and an account for each is required in order for an application to be submitted. If your organization is not listed in the dropdown menu, please email the Helpdesk (contact information in section 21.1) and provide the name of your organization. In most cases, this information will update in the system within 24 hours; however, it is advisable that this be performed as early as possible in the application process. An application cannot be submitted without ASO approval.
- The application must be submitted by the ASO on or before June 11, 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 PI.
- The application must be submitted on or before June 11, 2024, 4 PM central time.

3. APPLICATION PREPARATION AND SUBMISSION PROCESS

- The applicant completes/finalizes a series of numbered tabs of the application.
- Finalized tabs can be reset by the ASO.
- Once all tabs are finalized, the ASO reviews, approves, and submits the application to CPRIT.

4. APPLICATION/AUTHORIZED SIGNING OFFICIAL

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 PI.

As the organization's representative, the ASO is required to review the tabs finalized by the PI and subsequently submit the application. <u>Only the ASO is authorized to officially submit the application to CPRIT.</u> The ASO can reset PI-finalized tabs to draft at the request of the PI.

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 PI or the ASO can assign this individual to this role.

6. USER REGISTRATION AND/OR LOGIN

Applicants begin the application process by registering or logging into CARS (<u>https://cpritgrants.org</u>). On successful login into the system, applicants will be presented with the *My Applications* page. All prior submitted 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 & Research Institute of Texas	Home Help Desk FAQ Log Out
My Profile My	Applications Bridge Ny Grants Manage Organizations Current Funding Opportunities Feedback Review Grants HelpDesk Administrative	
Account Informati	an Centect Information Descriptive Information Biosketch	
	Logged in as: System Admin [mit] Home 2	System Admin click here My Profile > Account Info
	My Profile: Account Info	
	nformation is comprised of basic identification. You may edit this information at any time. rixed with * are required	
Role	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 application submission	
Salutation *	Ms. → Clicking on the button below will connect your profile in the Application Receipt System with ORCID. You will be note Sign in to your ORCID account if you already have one: if you do not have an ORCID Da all profile, you will be able	
First Name * Middle Initial	for one. Next, when you click the "Authorize" button, you will be asked to share your ID using an authenticated proc	
Last Name *	grant permission for CPRIT to securely obtain your ORCID ID and ensure that you are correctly identified.	
Suffix	III V (D Register or Connect your ORCID ID)	
Login/Usernam	ve SysAdmin	
Password	Update Password or Update Security Questions	
	Save Changes	

As directed by the modal window, during the initial login, on the "My Profile" page, the user is displayed a description of the authentication process and is invited through an ORCID-branded link to correlate his/her CARS and ORCID profiles. Note that the system will also provide identical functionality within the "Contacts" tab of all new applications.

Upon clicking on the ORCID-branded link, the system will open a new tab on the user's browser that will direct the user to enter his/her ORCID username and password. <u>Users without an</u> <u>ORCID account can initiate one from this window.</u>

Upon a successful login to the ORCID system, the user will be directed to a modal window that explicitly requests permission from the user to share his/her public ORCID profile with CARS.

If permission to correlate the 2 accounts has been provided by the authenticated user, the system then returns the user to the page from which the authentication started (ie, either the "My Profile" page or the "Contacts" tab of a new application). The system will then display a brief message confirming the authentication and replacing the ORCID-branded link with a new button that directs the user to his/her specific ORCID profile page.

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 → Individual Investigator Research Awards or Individual Investigator Research Awards for Prevention and Early Detection or Individual Investigator Research Awards for Cancer in Children and Adolescents Awards or Individual Investigator Research Awards for Clinical Trials or Individual Investigator Research Awards for Computational Systems Biology of Cancer or Individual Investigator Research Awards for Early-Onset Cancers → click New Application, or
- 2. Current Funding Opportunities → click FY 2025 Academic Research Programs → Individual Investigator Research Awards or Individual Investigator Research Awards for Prevention and Early Detection or Individual Investigator Research Awards for Cancer in Children and Adolescents or Individual Investigator Research Awards for Clinical Trials or Individual Investigator Research Awards for Computational Systems Biology of Cancer or Individual Investigator Research Awards for Early-Onset Cancers → click Start New Application.

Upon starting a new application, applicants are required to enter the title of the application (160character limit; can be edited later) 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.

Applicants are advised to carefully read the information on the summary page before moving on to the numbered tabs.

NOTE: A PI may submit only 1 application—a new, resubmission, or competitive renewal application—under these RFAs during this funding cycle.

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 4 (*Required Documents*) and Tab 5 (*Budget*).

8. STARTING A RESUBMISSION APPLICATION

Resubmission applications may be submitted for previously not funded Individual Investigator Research Awards, Individual Investigator Research Awards for Prevention and Early Detection, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Clinical Translation, and Individual Investigator Research Awards for Computational Systems Biology of Cancer 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. Options to "Select Resubmission Application Award Type" will appear on the screen. The appropriate award mechanism under which the resubmission will be submitted must be selected. After selecting the award mechanism, instructions and requirements for selected mechanism, as specified in the appropriate RFA, must be followed.

Note:

• An application submitted previously under another IIRA mechanism that addresses the goals of the new targeted RFA (IIRA-EOC) may be resubmitted once under the IIRA-EOC mechanism.

 An application submitted previously as Individual Investigator Research Awards for Clinical Translation may be resubmitted once under the RFAs new name: Individual Investigator Research Awards for Clinical Trials.

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.

IMPORTANT: 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. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.

NOTE: Only the title of the previously submitted application is prepopulated for a resubmission application. All other information, including the 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 15</u>: Tab 4, *Required Documents*).

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*) and Tab 5 (*Budget*).
- Tab 2 (*Application Information*) **must** be completed/finalized prior to Tab 4 (*Required Documents*) and Tab 5 (*Budget*).

9. STARTING A RENEWAL APPLICATION

Renewal applications may be submitted for funded Individual Investigator Research Awards, Individual Investigator Research Awards for Prevention and Early Detection, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Clinical Translation, and Individual Investigator Research Awards for Computational Systems Biology of Cancer. An application originally funded by CPRIT as an IIRA or IIRACB that is appropriate for the IIRAP, IIRACCA, IIRACT, or IIRACSBC mechanism may be submitted under RFA R-25.1-IIRAP, RFA R-25.1-IIRACCA, RFA R-25.1-IIRACCA, RFA R-25.1-IIRACT, R-25.1-IIRACSBC, or R-25.1-IIRA-EOC, respectively, for a competitive renewal.

Note:

- An application funded by CPRIT under another IIRA mechanism that addresses the goals of the new targeted RFA (IIRA-EOC) may be submitted once as a competitive renewal under the IIRA-EOC mechanism.
- An application funded by CPRIT as Individual Investigator Research Awards for Clinical Translation may be submitted once as a competitive renewal under the RFAs new name: Individual Investigator Research Awards for Clinical Trials.

Renewal applications can be started from the *My Applications* page by clicking the "Start Renewal Application" link of a previously funded application. Options to "Select Renewal Application Award Type" will appear on the screen. The appropriate award mechanism under which the renewal will be submitted must be selected. After selecting the award mechanism, instructions and requirements for selected mechanism, as specified in the appropriate RFA, must be followed.

Upon starting a renewal 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.

NOTE: Only the title of the previously funded Individual Investigator Research Award is prepopulated for a renewal application. All other information, including collaborators, and all required documents, must be submitted afresh.

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*) and Tab 5 (*Budget*).

• Tab 2 (*Application Information*) **must** be completed/finalized prior to Tab 4 (*Required Documents*) and Tab 5 (*Budget*).

10. STATUS DISPLAY

10.1. 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				
	sonnel Documents 5 Budget 6 Final Review & Submit				
Contacts Application ID: XXXXXXX	Phase: Full Application Status DRAFT				
Status	Status Definition				
DRAFT	The tab is being prepared by the applicant.				
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.				
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.				

10.2. 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 below).

11. TAB: SUMMARY

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

My Applications: Summary								
Summary		2 Application	3 Personnel & Collaborators	4 Required Documents	5 Budget	6 Final Review & Submit		
ummary pplication ID: XX	xxxxxx				Phase: Full Ap	olication		Statu C DRA
Application Title: screen shot Program: FY 2014 Research Programs Award Type: Individual Investigator Research Awards Please be sure to verify format requirements. Applications that do not meet format requirements and/or reviewers' determination of readability may result in rejection of your application. Please check the format requirements found in the <u>Request for Application (RFA)</u> Full Application Deadline: February 3, 2014 by 3:00 PM CT (<u>check current official time</u>) 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 a	and set to "PENDING	ASO APPROVAL	", the Application S		approve the application submission in order	
Section #	Application Section	ı					Status	
1	Contacts						draft	
2	Application Inf	ormation					draft	
3	Project Person	nel and Colla	borators				draft	
	Required Docu	uments					draft	
4								
4 5	Budget						draft	

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.

12. TAB 1: CONTACTS

- **Contact Principal Investigator (Required):** Verify information for the Contact PI; update as necessary. The Contact PI is responsible for the submission of the application, all reporting requirements, and all budgeting decisions.
- **Multi-Principal Investigator (MI) (Optional):** Any MIs must be added under this Tab. If additional MIs (MI application) are to be designated on the application, follow these steps:
 - Click the *Search for Principal Investigator* 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 or spelling variations). Alternatively, the individual may be invited to register in CARS and be part of the application by clicking the *Send Invitation* link. On the subsequent page, complete the fields and click the *Send Invitation* button. When this individual joins the application as a PI, his/her information will be listed in the appropriate section of the tab.
 - Change or remove an individual by clicking the appropriate button.
- Alternate Submitter (Optional): An alternate submitter may be designated on the application by the PI. Follow the search guidelines above.
- Application Signing Official (Required): An ASO <u>must</u> be listed in order to complete/finalize this tab. Click the *Search for Application Signing Official* button. Follow the search guidelines above.
- 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 PI 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, "Contact Principal Investigator," "Application Signing Official," and "Grants Contract/Office of Sponsored Projects Official" have been completed. PI information is entered automatically; an ASO must be identified and added by the PI. The Grants Contract/Office of Sponsored Projects Official may be identified and added by the PI or the ASO.

13. 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, Resubmission, or Renewal, as applicable).
- Application Title: The application title is stated. Edit if necessary.
- Category of research/project to be supported: Select the appropriate option for whether the proposed project will be directed toward childhood and adolescent cancer. If Yes is selected, provide a brief description of the childhood and adolescent focus.
- **TREC Eligibility:** Select the appropriate option based on your institution's eligibility as a Texas Regional Excellence in Cancer (TREC) institution. (See <u>Appendix 3</u>)
- **Project Information:**
 - Contract Start Date (m/d/yyyy): The contract start date of 3/1/2025 is prepopulated.
 - Proposed End Date (m/d/yyyy): Enter the proposed end date of the project. The maximum duration is 3 years (36 months) for IIRA, IIRA-EOC, and IIRACSBC applications, and 4 years (48 months) for IIRACCA, IIRAP and IIRACT applications.
- **Product Development:** Select "Yes" if the proposed research will lead to the development of a product that requires regulatory filing.
- 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.

- **Prevention Research Focus:** If you apply for the Individual Investigator Research Awards for Prevention and Early Detection, please indicate if you are applying for clinical research or population-based research.
- **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 maximum of <u>3</u>. If the focus of the project is not on a specific cancer focus, select All Cancers. The selection of cancer focus in this section assists CPRIT with reporting on cancer research that is being performed.
- 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, ethnicity, and race 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 institution. Use the link provided to find this information using the applicant's institutional address.
 - **State House District:** Enter the State House District of your institution. Use the link provided to find this information using the applicant's institutional address.
- Cancellation of Applications/Awards by Granting Organization (in past 5 years):
 - Select whether the PI is currently eligible to receive federal grant funds. If "No" is selected, provide a reason.
 - Select whether the PI 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 PI 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 PI.

14. TAB 3: PROJECT PERSONNEL AND COLLABORATORS

Investigators and Submitters

- Please make sure that the Contact PI and any MIs added under Tab 1 are appropriately listed here.
- **Contact Principal Investigator:** The Contact PI will be responsible for the submission of the application, all reporting requirements, and all budgeting decisions.
- Multi-Principal Investigator (s): MIs are allowed to be added for projects that require a team science approach. A person may be a Principal Investigator on only <u>1</u> application under RFA R-25.1-IIRA, RFA R-25.1-IIRACSBC, RFA R-25.1-IIRACCA, RFA R-25.1-
- All Principal Investigators, Contact PI and MIs, must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and must be a full-time resident of Texas during the time the research that is the subject of the grant is conducted.

• Please note that the biosketch for the Contact PI and Additional PIs (if designated) must be uploaded under the *Required Documents* tab (see section 15). Biosketches previously uploaded in *My Profile* will not be included in the application.

Project Personnel and Collaborators

- It is your responsibility to enter information for all project personnel, paid or unpaid, including any Coinvestigators and collaborators.
- Please ensure that all roles listed for a specific person under this tab match the role listed for that person under the Budget for All Key Personnel tab.
- <u>A Coinvestigator</u> is an individual involved with the Contact PI in the scientific development or execution of a project. The Coinvestigator may be at the same institution as the Contact PI or at another organization in Texas. A Coinvestigator should have a specific level of effort dedicated to the project and is considered senior/key personnel.
- <u>A collaborator</u> is an individual who contributes to the scientific or business development or execution of the project but is not responsible for leadership or accountability for managing the project. A collaborator can be paid or unpaid.
- The purpose of this section is for reviewers to be able to determine if they have any conflicts of interest with any of the listed individuals, at which point they would be required to recuse themselves from the review of the application. Select the appropriate *Role for Application* from the drop list. Click the *Save as Draft* button to save additions.

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.

15. 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: Abstract and Significance and Layperson's Summary: Enter the Abstract and Significance (5,000 characters) and Layperson's Summary (2,000 characters) of the proposed work. <u>Character limits include letters, spaces, and</u> <u>punctuations</u>. 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 else the Abstract and Significance and/or Layperson's Summary will be lost when the upload refreshes the Web page.

- Specific Aims and Subaims: Please enter your specific aims and subaims as plain text (1,200 characters per aim and per subaim). Please provide a description of the aims and subaims and milestones to be achieved for each year of the project. Provide 2 to 3 sentences describing activities to be performed and anticipated milestones. Specific aims and subaims will be reviewed during the evaluation of annual progress reports. HTML formatting, tables, charts, and diagrams are not supported. Specific aims and subaims may be saved as a DRAFT at any time by clicking the *Specific Aims and Subaims as Draft* button. Any unsaved aims and subaims will be lost.
 - At least 1 specific aim and 1 subaim are required. At least 1 subaim is required per specific aim. Up to 5 specific aims and 5 subaims per specific aim may be entered.
 - Click the Add Subaim link to add an additional subaim to a specific aim
 - Click the *Add Specific Aim* link to add additional specific aims.
- **Timeline** (1 page).: Upload Timeline PDF document Timeline will be reviewed during the evaluation of annual progress reports.
- Specific Aims (1 page): Upload the Specific Aims page document). See RFA for details and template provided in CARS under *Current Funding Opportunities*.
- **Resubmission Summary (2 pages).:** Upload the Resubmission Summary PDF document This option is available for resubmission applications only. Resubmissions of renewals will need to submit a separate Renewal Summary document.
- Renewal Summary (2 pages).: Upload the Renewal Summary PDF document This option is available for renewal applications and resubmissions of renewals. Describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the Renewal Summary.

- Summary Checklist: Upload the required checklist. The required template is provided in CARS under <u>Current Funding Opportunities</u>. <u>This requirement is for IIRACT</u> <u>applications only</u>.
- Research Plan: Upload the Research Plan PDF document (up to 10 pages for IIRA, IIRAP, IIRACCA, IIRA-EOC, and IIRACSBC; up to 11 pages for IIRACT). See RFA for details.
- Vertebrate Animals (1 page).: Upload the Vertebrate Animals PDF document If not applicable, upload a page with the following statement: "No vertebrate animals will be used."
- Human Subjects (2 pages): Upload the Human Subjects PDF document. If not applicable, upload a page with the following statement: "No human subjects will be used."
- **Protocol Documentation:** If applicable, upload the clinical trial protocol PDF document. <u>This requirement is for IIRACT applications only</u>.
- Investigational New Drug Application (IND)/Investigational Device Exemption (IDE): If applicable, upload the IND/IDE PDF document. <u>This option is for IIRACT</u> applications only.
- **Publications/References:** Upload the Publications/References PDF document. Copies of journal articles are <u>not allowed</u> under this section.
- **Contact PI Biosketch (up to 5 pages):** Upload the PDF biosketch of the Contact PI. NIH biosketches may be used.
- **PI Biosketch (up to 5 pages each):** If MIs have been designated (MI application) for the application, upload a PDF biosketch for the MI here. NIH biosketches may be used. If more than 1 biosketch is 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 5 additional Key Personnel: If desired, <u>up to 5 additional</u> <u>biographical sketches</u> for key personnel may be provided (use the template posted under the *Summary* tab or a NIH biosketch). Biosketches must <u>not</u> exceed 5 pages for each individual. If 5 biosketches are being provided, these must be combined into a single file

and submitted as a single PDF document (i.e., a 25-page document consisting of five 5-page biosketches).

- Current and Pending Support: For all personnel for whom a biosketch is submitted with the application, upload their current and pending support (use the template posted under the *Current Funding Opportunities*). Do not provide current and pending support for individuals for whom a biosketch was not included in the application. Multiple documents must be combined and submitted as a single PDF document. At a minimum, the current and pending support of the Contact PI and any MIs must be included in this document. Each Current and Pending Support document must include the corresponding Investigator's name at the top of the page.
- Institutional/Collaborator Support and/or Other Certification (up to 4 pages).: If applicable/desired, upload letters of institutional and/or collaborator support and other certification documents Multiple letters/files must be combined and submitted as a single PDF document. 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 justification of the budget for the entire proposed period of support for the</u> entire program and 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 subaward must itemize project charges for all charge</u> <u>categories</u>. (See also <u>section 16.4</u>). Invoices or sale quotes should not be included. When describing personnel roles (Coinvestigator, Collaborator, etc.) please make sure that they match that person's role in Tab 3: Project Personnel and Collaborators and the Budget for All Project Personnel tab.
- Summary Statement of Previous Application: If a summary statement was prepared for the previous application, it will be automatically uploaded as part of a resubmission application.

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

16. 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 <u>Individual Investigator Research Awards</u>, an applicant may request \$300,000 per year, inclusive of direct and indirect charges, for up to 3 years.
- For <u>Individual Investigator Research Awards for Early-Onset Cancers</u>, an applicant may request \$300,000 per year, inclusive of direct and indirect charges, for up to 3 years.
- For <u>Individual Investigator Research Awards for Prevention and Early Detection</u>, an applicant may request a maximum up to \$300,000 in total costs per year for up to 4 years for clinical or population-based research, including implementation or dissemination research.
- For <u>Individual Investigator Research Awards for Cancer in Children and Adolescents</u>, an applicant may request a maximum of \$300,000 per year, inclusive of direct and indirect charges, for a period of up to 4 years.
- For <u>Individual Investigator Research Awards for Clinical Trials</u>, an applicant may request a maximum of \$400,000 per year, inclusive of direct and indirect charges, for a period of up to 4 years. Note that an individual detailed budget for conducting a clinical trial is required. Note this mechanism supports applications that propose innovative cancer clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial.
- For Individual Investigator Research Awards for Computational Systems Biology of <u>Cancer</u>, an applicant may request \$350,000 per year, inclusive of direct and indirect charges, for up to 3 years.

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.

16.1. Budget for All Project Personnel (use Web form provided)

Complete the requested information.

First Name and **Last Name**: The Contact PI and any MI's name[s] (as applicable) are 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 Contact PI and any MI's role (as applicable) are prepopulated. Enter roles of other individuals as necessary. Please make sure that the individual's role matches their role entered under Tab 3: Project Personnel and Collaborators and their role in the Budget Justification document.

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

Annual Base Salary: For each individual listed, enter his/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 16.5, Salary Cap. If a PI is being paid through a subcontract award, enter a \$0 amount in the Annual Base Salary field and the Salary Requested field. Their salary can be included in the Contractual (Subaward/Services Contracts) section of the detailed budget.

Effort on Project: For each individual listed, enter his/her percent effort on the project. For applications that do not include MIs, the PI is required to maintain a minimum 15% level of effort throughout the entire award period. For applications that include MIs, each MI/PI is required to maintain a minimum 10% effort for each throughout the entire award period. <u>An individual's effort on the project must be entered here even if they will be paid through a subcontract award and their salary is entered as \$0.</u>

Salary Requested: After entering the information in these categories, click "Calc" to autocalculate the requested salary. If a PI is being paid through a subcontract award, enter a \$0 amount in the Annual Base Salary field and the Salary Requested field. Their salary can be included in the Contractual (Subaward/Services Contracts) section of the detailed budget.

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

16.2. Detailed Budget for Year 1

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

Travel Costs: Include any costs associated with necessary travel. CPRIT funds may be used to send up to 2 people to CPRIT's biennial conference. 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): Itemize each piece of equipment having a useful life of more than 1 year and an acquisition charge of \$5,000 or more per unit that is anticipated to be purchased for use in the project. Each piece of equipment must be approved by CPRIT in the

application or after the project is funded. If the project is funded, approval may be requested during the period a grant is active and will be considered on a case-by-case basis. However, any proposed equipment purchase in an application removed by a peer review panel will not be reconsidered if the project is funded.

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 PI 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 clinical trials or animal care charges for animal studies that will not be paid through a contractual arrangement Funds can be used to pay for costs that a cancer clinical trial participant may have associated with their participation in a clinical trials, including (1) transportation, including car mileage, parking, bus fare, taxi or ride hailing fare exclusive of tips, and commercial economy class airfare within the borders of the State of Texas and (2) lodging.

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 towards 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.

16.3. 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). Cost adjustments of up to a 3% annual increase for salary up to the cap of \$225,000 are permitted for Years 2 and 3 (Years 2 through 4 for IIRACCA and IIRAP).

Note that for the IIRAP, and IIRACT, while there will be 1 budget for the entire project, an individual budget and budget justification for the conduct of a clinical trial must be included. The justification should include the statistical considerations that led to the clinical trial design, accrual milestones, and validation of biomarkers.

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).

16.4. Budget Justification

Provide a <u>brief 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, contractual charges, other expenses and indirect charges. <u>Each subaward must itemize charges</u> <u>for all budget categories</u>. If more than the maximum dollar amount is requested in any year(s) of the proposed budget of an application, include a special and clearly labeled section that explains the request. If you uploaded this document under Tab 4 (*Required Documents*) (see <u>section 15</u>), you can click on the link directing you to your uploaded file. If you have not uploaded this document, please click on the link that will direct you to Tab 4 (*Required Documents*) where you can upload this file.

16.5. 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/her institutional salary based on effort on a project.

The following table outlines the salary cap guidelines; note that the maximum salary for levels of effort below 100% are 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 applicant
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

17. TAB 6: FINAL REVIEW & SUBMIT

When Tabs 1 through 5 have been completed and finalized by the applicant, 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 PI's institution must submit the application by the submission deadline: June 11, 2024, 4 PM central time.

18. 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)
- <u>IIRACT Summary Checklist</u> (.doc, .PDF)

In addition, a template is provided for the biographical sketch, but an NIH biographical sketch may be used if desired. A template is also provided for the Specific Aims page <u>here</u>.

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

19. VERTEBRATE ANIMALS/HUMAN SUBJECTS

Whenever vertebrate animals or human subjects are part of a CPRIT-funded project, a copy of the recipient organization's Institutional Review Board (IRB) and/or Institutional Animal Care and Use Committee (IACUC) approval must be provided to CPRIT before funding can be released. For multiyear projects, annual confirmation of IRB or IACUC approval is required. This information is not required at the time of submission of the application.

20. FORMATTING INSTRUCTIONS

All sections of the application should be written in clear and legible text and must follow the guidelines described below. Applicants 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. 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 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: Besides page numbers, these should not be used unless they are part of a provided template. Page numbers may be included in the footer.
- Supplemental ("Appendix") Material: These are permitted only if certification documents and/or clinical trial protocols are vital to the evaluation of the proposed research study. Applicants are strongly advised not to submit publications, figures, and/or data.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

21. CONTACT INFORMATION

21.1. 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 the CPRIT Application Receipt System. Helpdesk staff cannot answer scientific questions and/or Academic Research programs aspects of an application.

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

Tel: 866-941-7146

Email:Help@CPRITGrants.org

21.2. Scientific and Programmatic Questions

Scientific and Programmatic Questions should be directed to the CPRIT Director of Academic Research. Contact the Helpdesk for any items related to the Application Receipt System (CARS), page limitations, formatting, etc.

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

Appendix 1: DESCRIPTION OF RESEARCH AREAS

In <u>Tab 2</u> (*Application Information/Application Classification*) the 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, 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 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, and 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, zebrafish, *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 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*. 85:470-475, 2010.

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 Texas Regional Excellence in Cancer (TREC)-eligible institution.

TREC-Eligible Institutions are:

- 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