



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS
INSTRUCTIONS FOR
APPLICANTS

Individual Investigator Research Awards
RFA R-15-IIRA-1

**Individual Investigator Research Awards for Prevention and
Early Detection**
RFA R-15-IIRAP-1

**Individual Investigator Research Awards for Cancer in
Children and Adolescents**
RFA R-15-IIRACCA-1

FY 2015

Fiscal Year Award Period
September 1, 2014 – August 31, 2015

TABLE OF CONTENTS

1. INTRODUCTION.....	5
2. SUMMARY INSTRUCTIONS	5
3. APPLICATION SUBMISSION DEADLINE	6
4. APPLICATION PREPARATION AND SUBMISSION PROCESS.....	6
5. APPLICATION/AUTHORIZED SIGNING OFFICIAL (ASO).....	6
6. GRANTS CONTRACT/OFFICE OF SPONSORED PROJECTS OFFICIAL.....	7
7. USER REGISTRATION AND/OR LOGIN.....	7
8. STARTING A NEW APPLICATION	8
9. STARTING A RESUBMISSION APPLICATION.....	8
10. STARTING A RENEWAL APPLICATION.....	10
11. STATUS DISPLAY	11
11.1. Tab Status.....	11
11.2. Application Status.....	11
12. TAB: SUMMARY	12
13. TAB 1: CONTACTS.....	13
14. TAB 2: APPLICATION INFORMATION.....	14
15. TAB 3: COLLABORATORS AND CONFLICTS OF INTEREST.....	17
16. TAB 4: REQUIRED DOCUMENTS.....	17
17. TAB 5: BUDGET.....	20
17.1. Senior/Key Person & Other Personnel	21
17.2. Detailed Budget for Year One	22
17.3. Budget for Entire Proposed Period of Performance	23
17.4. Budget Justification	24
17.5. Salary Cap.....	25
18. TAB 6: FINAL REVIEW & SUBMIT	26
19. PRODUCT DEVELOPMENT.....	26
20. PROVIDED TEMPLATES.....	26
21. VERTEBRATE ANIMALS/HUMAN SUBJECTS	27
22. FORMATTING INSTRUCTIONS.....	27
23. CONTACT INFORMATION.....	29
23.1. HelpDesk.....	29

23.2. Scientific and Programmatic Questions..... 29

24. APPENDIX 1: DESCRIPTION OF RESEARCH AREAS 30

25. APPENDIX 2: PROGRAM FOCUS - DEFINITIONS OF CANCER RESEARCH
TYPES 31

VERSION HISTORY

Rev 5/15/14 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 (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-15-IIRA-1), Individual Investigator Research Awards for Prevention and Early Detection (RFA R-15-IIRAP-1), and Individual Investigator Research Awards for Cancer in Children and Adolescents (RFA R-15-IIRACCA-1). Applications may be submitted from May 15, 2014, through June 26, 2014.

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 23.1](#)) 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:** Use the provided templates for biographical sketches (biosketches), the product development plan, and current and pending support.
- **Product Development Plan:** A product development plan is required for proposed research that will lead to the development of a product that requires regulatory filing.

- **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 application must be submitted by the ASO on or before June 26, 2014, 3 p.m., Central Time.
- **Note:** CARS will be unavailable the third Thursday of each month between 7 p.m. and 9 p.m. 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.

3. APPLICATION SUBMISSION DEADLINE

The application must be submitted **on or before June 26, 2014, 3 p.m. Central Time.**

4. 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.

5. 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 PI.

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

6. 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.

7. USER REGISTRATION AND/OR LOGIN

Applicants begin the application process by registering or logging into CARS (<https://cpkritgrants.org>). On successful login into the system, applicants will be presented with the *My Applications* page shown on the next 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. A biosketch is required for the PI and the Co-Principal Investigator (Co-PI).

The screenshot shows the 'My Applications' page of the CPRIT Application Receipt System. The page header includes the CPRIT logo and the text 'CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS Application Receipt System'. A navigation menu at the top contains links for 'My Profile', 'My Applications', 'My Grants', 'Manage Organization Agreements', 'Current Funding Opportunities', 'Feedback', 'Review Grants', and 'HelpDe'. Below this is a secondary menu with 'Administrati', 'Application List', 'Start New Application', and 'Reporting'. The main content area is titled 'My Applications' and includes a login status 'Logged in as: System Admin [not System Admin.cli]'. A filter section allows users to show 'All Applications' or 'All My Roles', filter by 'Since FY' (FY 2014) or 'Only For FY', and select application statuses: Draft, Pending ASO Approval, Pending Responsiveness Review, ASO Approved and Submitted, and Deleted/Withdrawn. A 'Refresh List' button is also present. Below the filter section, a table header is visible with columns: Application ID, Type**, Title, Applicant, My Role, Due Date, Status, Funding Status, and Actions.

8. STARTING A NEW APPLICATION

New applications can be started in one of two ways:

1. My Applications (this is the default page after login) → click *start a new application* → FY 2015 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 → click *New Application*, or
2. Current Funding Opportunities → click *FY 2015 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 → click *Start New Application*.

Upon starting a new application, applicants are required to enter the title of the application (160 character 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. 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 (Collaborators & COIs).
- Tab 2 (Application Information) **must** be completed/finalized prior to Tab 4 (Required Documents) and Tab 5 (Budget).

9. STARTING A RESUBMISSION APPLICATION

Resubmission applications may be submitted for previously not funded Individual Investigator Research Awards applications only. Because Individual Investigator Research Awards for Prevention and Early Detection and Individual Investigator Research Awards for Cancer in Children and Adolescents are the new mechanisms, resubmission is not available under RFA R-15-IIRAP-1 and RFA R-15-IIRACCA-1. If a previously unfunded IIRA application is responsive to the IIRAP or IIRACCA RFA, it may be submitted as a new applications under one of these award mechanisms.

An IIRA 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.

IMPORTANT: More than one 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 Applicant or company representative for a 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 Co-PI, collaborators, COIs, and all required documents must be submitted afresh. If a summary statement was prepared for the previous application, it will be automatically uploaded as part of the resubmission application (see [Section 16](#): 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 (Collaborators & COIs).
- Tab 2 (Application Information) **must** be completed/finalized prior to Tab 4 (Required Documents) and Tab 5 (Budget).

10. STARTING A RENEWAL APPLICATION

Renewal applications may be submitted for funded Individual Investigator Research Awards. An application originally funded by CPRIT as an IIRA that is appropriate for the IIRAP or IIRACCA mechanism may be submitted under RFA R-15-IIRAP-1 or RFA R-15-IIRACCA-1, respectively, for a competitive renewal.

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 the Co-PI, collaborators, COIs, 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 (Collaborators & COIs).

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

11. STATUS DISPLAY

11.1. 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.



Status	Status Definition
DRAFT	The tab is being prepared by the applicant.
PENDNG ASO APPROVAL	The tab has been finalized by the applicant. When all tabs are finalized and reflect this status, the ASO will receive e-mail 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 e-mail.

11.2. 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).

12. 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 Collaborators & COIs
4 Required Documents
5 Budget
6 Final Review & Submit

Summary
 Application ID: RPXXXXXX Phase: Full Application Status: DRAFT

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 [Request for Application \(RFA\)](#).

Full Application Deadline: 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	Collaborators & Conflicts of Interest	draft
4	Required Documents	draft
5	Budget	draft
6	Final Review and Submit	NOT APPROVED

Section	Status	Status Definition
	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 e-mail notification that the application can be reviewed/submitted. The applicant is included on this notification.
	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.

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.

13. TAB 1: CONTACTS

- **Principal Investigator:** Verify information for the PI; update as necessary.
- **Co-Principal Investigator (Optional):** Only one Co-PI may be designated on an Individual Investigator Research Award application. If a Co-PI is to be designated on the application, follow these steps:
 - Click the *Search for Co-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 Co-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 must 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:** A Grants Contract/Office of Sponsored Projects Official must 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 three required fields of this section, namely, “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.

14. 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.

- **Project Information**

- **Contract Start Date (m/d/yyyy):** The contract start date of 3/1/2015 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 and IIRAP applications and 4 years (48 months) for IIRACCA applications.

- **Product Development:** If the proposed research will lead to the development of a product that requires regulatory filing (see [Section 19](#)), applicants must complete the Product Development Plan (use the template posted under the *Summary* tab). This document must be submitted via Tab 4 (Required Documents).

- **Application Classification:**

- **Research Area:** Select the research area that best describes the proposed work. Please refer to the *Appendix* ([Section 24](#)) 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 laboratory and clinical research or population-based research.
- **Program Focus:** Select the focus of the proposed work. Please refer to Appendix 2 ([Section 25](#)) for the definitions of cancer research types.
- **Cancer Site Addressed:** Select the cancer site(s) that will be addressed during the proposed project and that most closely represents the focus of your work. The selection of cancer sites in this section assists CPRIT with reporting on cancer research that is being performed. If the proposed project relates to all cancer types or focuses on general cancer research, select “All Sites” from the list. If the proposed project focuses on multiple cancer sites, but not all sites, please select only the sites for which actual work will be performed. If the proposed project is related to cancer of the esophagus, please select “Head and Neck” from the list.
- **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 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 one priority may be selected. If choice 5 is selected, then enter the name of the research sponsor and the sponsor’s priority that the application addresses.

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.

15. TAB 3: COLLABORATORS AND CONFLICTS OF INTEREST

- **Investigators and Submitters:** Ensure that biosketches for the PI and Co-PI (if designated) are uploaded. If the biosketches are missing, they can be uploaded under the *My Profile* link via that individual's account. This tab cannot be finalized without the biosketch of the PI and Co-PI (if designated).

Please note that the Biosketch that is in *My Profile* when Tab 3 (Collaborators & COIs) is finalized will be reflected in the final application. Please make sure that you make any updates in the Biosketch before finalizing this Tab. Any changes after this point will be saved in *My Profile* but will not be copied to the final version of this application.

- **Collaborators and Conflicts of Interest (COIs):** Enter information for all collaborators and COIs (select the appropriate *Role for Application* from the drop list). Click the *Save as Draft* button to save additions.
- **Collaborators Listed:** Review the list to ensure that all entered collaborators have been successfully added.
- **Conflicts of Interest (COIs) Listed:** Review the list to ensure that all entered COIs have been successfully added.

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

16. 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. Character limits include letters, spaces, and punctuations. Do NOT use symbols or special characters (e.g., 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.
- **Goals and Objectives:** Please enter your Goals and Objectives as plain text (1,200 characters per Goal and per Objective). Goals and Objectives will be reviewed during the evaluation of annual progress reports. HTML formatting, tables, charts, and diagrams are not supported. Goals and Objectives may be saved as a DRAFT at any time by clicking the “Goals and Objectives as Draft” button. Any unsaved Goals and Objectives will be lost.
 - At least one Goal and one Objective are required. At least one Objective is required per Goal. Up to 5 Goals and 5 Objectives per Goal may be entered.
 - Click the *Add Objective* link to add an additional Objective to a Goal.
 - Click the *Add Goal* link to add additional Goals.
- **Timeline:** Upload Timeline PDF document (1 page). Timeline will be reviewed during the evaluation of annual progress reports.
- **Resubmission Summary:** This is applicable for IIRA Resubmissions only. Upload the Resubmission Summary PDF document (1 page). This option is available for resubmission applications only.
- **Renewal Summary:** Upload the Renewal Summary PDF document (2 pages). This option is available for renewal applications only. Describe and demonstrate that appropriate/adequate progress 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 the Renewal Summary.

- **Research Plan:** Upload the Research Plan PDF document (up to 10 pages) (see RFA for details).
- **Vertebrate Animals and/or Human Subjects:** Upload the Vertebrate Animals and/or Human Subjects PDF document (1 page). If not applicable, upload a page with the following statement: “No vertebrate animals and/or human subjects will be used.”
- **Publications/References:** Upload the Publications/References PDF document.
- **Biographical Sketches of two additional Key Personnel:** If desired, up to two additional biographical sketches for key personnel may be provided (use the template posted under the *Summary* tab). Biosketches must not exceed 2 pages for each individual. If two biosketches are being provided, these must be combined into a single file and submitted as a single PDF document (i.e., a 4-page document consisting of two 2-page biosketches.)

Biosketches of the PI and the Co-PI (if designated) are extracted from their respective profiles and are automatically part of the application; these should not be part of this document.

- **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 *Summary* tab). Multiple documents must be combined and submitted as a single PDF document. At a minimum, the current and pending support of the PI and Co-PI (if designated) must be included in this document.
- **Product Development Plan:** If applicable, upload the Product Development Plan PDF document. The Product Development Plan must be submitted as a single PDF document.
- **Institutional/Collaborator Support and/or Other Certification:**
If applicable/desired, upload letters of institutional and/or collaborator support and other certification documents (up to 4 pages). Multiple letters/files must be combined and submitted as a single PDF document. Applicants are strongly advised not to submit “appendix material,” such as publications, figures, and/or data.

- **Clinical Trial Plan:** If you are planning to conduct clinical trials as part of your proposed project, please submit required documentation as a single PDF file via e-mail to the CPRIT HelpDesk at help@CPRITgrants.org. In this document, please include the clinical trial protocol, informed consent document, and a letter of drug availability from the sponsor if the trial is using an investigational drug. CPRIT may require institutional review board (IRB) approval prior to the initiation of funding.
- **Summary Statement of Previous Application:** Applicable for IIRA Resubmissions only. If a summary statement was prepared for the previous application, it will be automatically uploaded as part of a resubmission application. Applicants can view the summary statement prior to finalizing the section. If a summary statement was not prepared, no document is uploaded.

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

17. TAB 5: BUDGET

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

The budget section is composed of four subtabs:

1. Senior/Key Person & Other Personnel
2. Detailed Budget for Year One
3. Budget for Entire Proposed Period of Performance
4. Budget Justification

All four subtabs must be completed to finalize this section. A detailed budget for the first year of the project is required.

- For Individual Investigator Research Awards, an applicant may request \$300,000 per year, inclusive of direct and indirect charges, for up to 3 years.
- For Individual Investigator Research Awards for Prevention and Early Detection, an applicant may request \$500,000 per year, inclusive of direct and indirect charges, for up to 3 years for laboratory and clinical research and up to \$1,000,000 in total costs per year for up to 3 years for population-based research.

- For Individual Investigator Research Awards for Cancer in Children and Adolescents, the applicants may request a maximum of \$500,000 per year, inclusive of direct and indirect charges, for a period of up to 4 years.

Exceptions to the limits per year may be requested if extremely well justified (see Sections 4 of the RFAs).

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.

17.1. Senior/Key Person & Other Personnel

Complete the requested information.

First Name and Last Name: The 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 PI's role is prepopulated. Enter roles of other individuals as necessary.

Type Appt. (Months): For each individual listed, enter their appointment type, e.g., 6-month, 9-month, 12-month appointment.

Annual Base Salary: For each individual listed, enter their institutional base salary. The salary cap for CPRIT awards for FY 2015 (September 1, 2014, through August 31, 2015) is \$200,000; see [Section 17.5](#), Salary Cap.

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

17.2. Detailed Budget for Year One

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

Travel: Include any project-related travel charges. CPRIT cannot support patient-related travel charges. CPRIT funds may be used to send up to two people to CPRIT’s annual conference.

Equipment (400-character limit): Itemize as necessary. Equipment having a useful life of more than 1 year and an acquisition charge of \$5,000 or more per unit must be specifically approved by CPRIT. Preapproval is not required; if the project is funded, approval may be requested at that time.

Supplies (800-character limit): Itemize by category as necessary.

Consultant Charges: State charges for consulting services that may be used during the proposed work.

Contractual (Subaward/Consortium) (400-character limit): Itemize all subaward- and consortium-associated amounts. State direct charges only. Each subaward must be itemized in the *Budget Justification* subtab by stating project charges for personnel, travel, equipment, supplies, consultants, research-related subjects, and other expenses.

Research-Related Subject Charges: Enter charges associated with subjects related to the proposed work (e.g., charges associated with participation of human subjects in clinical trials). CPRIT cannot support patient-related travel charges.

Other (800-character limit): Itemize other project-associated expenses.

Indirect Charges: CPRIT limits indirect charges to a maximum of 5 percent. Total Indirect Charges for Year One (line D) should not exceed 5 percent of the Total Charges for Year One (line E). 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 for Subawards: Subawards may recover indirect charges of up to the maximum of 5 percent of the total requested subaward amount. However, because CPRIT awards will be made to the primary institution (which, in turn, will manage the subcontracts), the indirect charges for each subcontract are calculated as part of the total amount requested by the primary institution. Do not include indirect charges in the Contractual (Subaward/Consortium) category. The appropriate subaward amount—including the allowable indirect charges—will be forwarded to the subcontracting institution by the primary institution.

17.3. Budget for Entire Proposed Period of Performance

Amounts for *Budget Year One* will be autopopulated based on the information provided on the previous subtabs, namely, *Senior/Key Person & Other Personnel* and *Detailed Budget for Year One*. 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 percent of the salary (a warning will be displayed). Cost adjustments of up to a 3-percent annual increase for salary and other categories are permitted for Years 2 and 3. A 3-percent salary increase for Years 2 and 3 is permitted up to the cap of \$200,000. The salary cap ([Section 17.5](#)) 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 percent of the total requested award amount for that year (sum of lines C and D). Calculate as follows: Total Indirect Charges = (Total Direct Charges/0.95) – Total Direct Charges.

17.4. Budget Justification

Provide a brief and concise justification of the budget (15,000-character limit) 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. **Each subaward must itemize project charges for all charge categories.** 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.

NOTE: If the text for the budget justification is prepared using Microsoft Word, applicants are advised to first copy and paste this text into a plain-text editor such as Notepad or WordPad (to remove all formatting) before copying and pasting it into the receipt system's text entry field. The following is an example of minimal formatting that translates cleanly to the final output of the budget section of the application. Headings in upper case, no bullets, and an additional hard return between paragraphs and sections improve legibility. No tabs or tables are used.

HEADING 1

* <Justification itemization 1>

* <Justification itemization 2>

HEADING 2

Sub-Heading 2.1

<Justification text>

Sub-Heading 2.2

<Justification text>

HEADING 3

<Justification text>

17.5. Salary Cap

The salary cap for CPRIT awards in FY 2015 (September 1, 2014, through August 31, 2015) is \$200,000. Thus, the maximum direct salary support an individual can request is up to \$200,000 of their institutional salary based on effort on a project:

- With 100 percent effort on the project, individuals with an institutional base salary of less than \$200,000 would request the entire base salary amount.
- With 100 percent effort on the project, individuals with an institutional base salary of more than \$200,000 would request the salary cap of \$200,000.
- With 50 percent effort on the project, individuals with an institutional base salary of more than \$200,000 would request \$100,000.

The following table outlines the salary cap guidelines. 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 \$200,000	1–100%	Up to base salary
More than \$200,000 (e.g., \$300,000)	100%	\$200,000
More than \$200,000 (e.g., \$300,000)	50%	\$100,000

18. 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 e-mail 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 or her *My Applications* page. To submit the application, the ASO must enter his or 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 26, 2014, 3 p.m., Central Time.**

19. PRODUCT DEVELOPMENT

If the proposed research will lead to the development of a product that requires regulatory filing, applicants must complete the Product Development Plan using the template provided (posted under the *Summary* tab).

20. PROVIDED TEMPLATES

Applicants must use the provided templates to prepare and submit the following documents. Templates are posted under the *Summary* tab and are available in .doc and .PDF format.

- Biographical Sketch (.doc, .PDF)
- Product Development Plan (.doc, .PDF)
- Current and Pending Support (.doc, .PDF)

21. 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 multi-year projects, annual confirmation of IRB or IACUC approval is required. This information is not required at the time of submission of the application.

22. 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 just include only text.

- **References:** Applicants should use citation style that includes the full name of the article and that lists at least the first three 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 Web sites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Add page numbers in the footer for each document that is uploaded as a PDF. Restart the page numbering at 1 for each document. Pages should be numbered at the bottom right corner of each page.
- **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.**

23. CONTACT INFORMATION

23.1. HelpDesk

HelpDesk support is available for technical questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff is not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: May 15, 2014, to June 26, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: ResearchHelp@CPRITGrants.org

23.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Manager for Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

24. APPENDIX 1: DESCRIPTION OF RESEARCH AREAS

In Tab 2 (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.
- **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.

25. APPENDIX 2: PROGRAM FOCUS - DEFINITIONS OF CANCER RESEARCH TYPES

In Tab 2 (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,” Acad. Med. 85:470–475, 2010.