



2015 PANCREATIC CANCER ACTION NETWORK TRANSLATIONAL RESEARCH GRANT

Program Guidelines and Application Instructions

**Please direct pre-award questions to:
Pancreatic Cancer Action Network
(310) 725-0025
grants@pancan.org**

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I. PROGRAM GUIDELINES

PROJECT FUNDING

In recognition of the urgent need to accelerate scientific and medical breakthroughs in pancreatic cancer and with the guidance of our scientific advisors, in February 2011 the Pancreatic Cancer Action Network (PanCAN) adopted a bold initiative to double survival for pancreatic cancer by the year 2020. For more information about this goal, see <http://www.pancan.org/section-about/vision-of-progress/>.

In an effort to facilitate achievement of this goal, PanCAN has introduced several new grant mechanisms to fund translational and clinical research. The 2015 Translational Research Grant is intended to continue the momentum on high priority pancreatic cancer research that is poised for important translational next steps in order to help move discovery to application in patients.

The Translational Research Grant will provide \$300,000 over two years to fund a translational research project that has as its endpoint the development of a pancreatic cancer assessment, prevention or treatment modality. The scientific validation of the proposed modality must already exist and the project proposed for funding should represent a practical application of this knowledge. Fundamental discovery or basic science research projects are not eligible for funding through this grant mechanism.

Applicants must be full time, independent junior or senior investigators. The type of project that will qualify for funding will typically benefit from the inclusion of cross-disciplinary expertise and collaboration. Therefore, applications can include one Contact-Principal Investigator (PI), or a Contact-PI and a Co-PI. If there are two PIs, it should include a basic scientist and a clinician. The Contact-PI is the applicant.

DEFINITION OF TRANSLATIONAL RESEARCH

For the purposes of this grant, translational research is defined according to the framework conceived by the Translational Research Working Group (TRWG). The TRWG was created in 2005 under the auspices of the U.S. National Cancer Advisory Board to evaluate the status of the National Cancer Institute's investment in translational research and enhance the translational research enterprise. (Before completing an application, researchers are encouraged to review the TRWG report *Transforming Translation: Harnessing Discovery for Patient and Public Benefit*, published in June 2007, and a series of seven articles published in the 2008 (Vol. 14, No. 18) issue of *Clinical Cancer Research*.)

The TRWG defined translational research as an iterative and multidirectional process that consists of applied research that transforms discoveries from fundamental laboratory, clinical or population-based research into new drugs, devices or interventions; as well as findings from the clinic and population that loop back and inform new research to refine or expand an innovation. The TRWG focus was on "early translational research" and specifically on the phases that follow scientific validation of a discovery up until definitive, late stage-trials.

Consistent with the TRWG framework, on a research translation continuum, the Translational Research Grant will support research that **follows** fundamental discovery, all the way through Phase I/II clinical trials. **Importantly, to be eligible for funding, the scientific validation, clinical application and need, and feasibility of developing the clinical modality must already be established and the supporting evidence must be submitted as part of the application process.**

The Translational Research Grant will support the following research phases: the development of enabling tools or technologies that are required to create the modality; the actual creation and refinement of the new modality; preclinical development; and/or initial validation of the modality in

humans to determine if there is sufficient evidence of safety and efficacy to warrant a definitive trial. See Project Eligibility below for additional important details.

IMPORTANT DATES

E-Application Deadline

Friday, January 30, 2015 at Noon, Eastern Time

Decision Date

May 2015

Grant Term

Start Date: July 1, 2015

End Date: June 30, 2017

Scientific Meeting

August 27-30, 2015, San Diego, CA and 2016 and 2017 (dates and location to be determined) – Grant recipients are required to attend, if invited. This is an annual series of activities that involve scientific and networking sessions for knowledge exchange, research feedback, mentorship, and collaborations. Also in attendance are other PanCAN grant recipients, members of PanCAN's Scientific and Medical Advisory Board and Board of Directors, donors, and the broader pancreatic cancer community. These opportunities have been effective in building a robust Community for Progress, comprised of multidisciplinary researchers dedicated to studying pancreatic cancer. Support for travel is provided by PanCAN separate from the grant.

APPLICANT ELIGIBILITY

Applicants must have a medical and/or doctoral degree (including PhD, MD, DO, PharmD, or equivalent doctoral degree) in the biomedical sciences or in a field applicable to health science research, and be affiliated with an academic, medical or research institution **within the United States**. There are no citizenship requirements; however, an applicant who is not a U.S. citizen or permanent resident, by submitting an application for this grant, assures that his/her visa status will provide sufficient time to complete the project and grant term within the United States.

The project supported by a Translational Research Grant is expected to benefit from collaboration between basic and clinical scientists. Therefore, if the Contact-PI is a basic scientist, a clinician/clinical scientist can be designated as a Co-PI on the proposed project. Or if the Contact PI is a clinical scientist, a basic scientist can be designated as a Co-PI. The Co-PI can be located at the same or at a different institution. The different institution can be within or outside the United States.

Researchers with active Pancreatic Cancer Action Network grants or who have submitted applications for a 2015 Pancreatic Cancer Action Network Research Acceleration Network Grant or Career Development Grant administered in partnership with AACR are also eligible to apply for a 2015 Translational Research Grant.

Only one application for a Translational Research Grant will be accepted per Contact-PI, though it is possible to serve as a Co-PI on another proposed project.

Employees or subcontractors of a government entity or for-profit industry are not eligible to be a PI but may serve as collaborators, though no grant funds may be directed towards these individuals.

Members of the 2015 Translational Research Grant Scientific Review Committee are not eligible to apply for this grant.

PROJECT ELIGIBILITY

The project proposed for a Translational Research Grant must build on progress already made in pancreatic cancer research and cannot consist of fundamental discovery or basic science research.

The below figure illustrates the TRWG framework which will be used to determine whether a project is ready and eligible for a Translational Research Grant.

Overview of the Six TRWG Pathways

DEVELOPMENTAL PHASE		MODALITY								
		RISK ASSESSMENT Research to characterize the cancer-related health status of an individual		INTERVENTIVE Research to change the cancer-related health status of an individual through prevention or treatment						
SUPPORTING TOOLS <input checked="" type="checkbox"/>	NO <input type="checkbox"/>	CREDENTIALING								
	<input checked="" type="checkbox"/>	I. BIOSPECIMEN-BASED		II. IMAGE-BASED		I. AGENTS (Drugs & Biologics)		II. IMMUNE RESPONSE MODIFIERS	III. INTERVENTIVE DEVICES	IV. LIFESTYLE ALTERATIONS
	<input checked="" type="checkbox"/>	CREATION OF MODALITY								
	<input checked="" type="checkbox"/>	PRECLINICAL DEVELOPMENT								
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	CLINICAL TRIALS								

Consistent with the TRWG framework, the proposed project must have as its endpoint a risk assessment or interventional clinical modality. Risk assessment modalities characterize the cancer-related health status of an individual, and include pancreatic cancer screening, detection, diagnosis, prognosis, or treatment response assessment. Interventional modalities change the cancer-related health status of an individual and deal with pancreatic cancer prevention or treatment.

Within the Risk Assessment modality, there are two pathways:

- I. **Biospecimen-based assays**, which involve biomarkers (e.g., DNA, RNA, protein, lipids, carbohydrates) for the detection, diagnosis or prognosis of pancreatic cancer or the assessment of response to treatment derived from any of a variety of biospecimens (e.g., blood, other body fluids or tissues).
- II. **Image-based techniques** (e.g., nanotechnology, fluorescence, MRI, PET) to analyze tissue noninvasively for the detection, diagnosis or prognosis of pancreatic cancer and pre-cancer; or to assess treatment response.

Within the Interventional modality, there are four pathways:

- I. **Drug or biologic agents** (e.g., novel chemotherapeutic compounds)
- II. **Immune response modifiers** (e.g., vaccines, cytokines)
- III. **Interventional devices** (e.g., novel surgical techniques, radiotherapy image-guided interventions)
- IV. **Life-style alterations** (e.g., modifying risk-related behaviors, changing environmental exposures)

Each of these six pathways is characterized by the following developmental phases:

- **Credentialing:** research that validates the modality; i.e., establishes a strong empirical basis for the clinical relevance of the discovery, its clinical need, and feasibility of being developed. Credentialing research does not qualify for a Translational Research Grant.

- **Development of supporting tools:** research that develops collateral tools, techniques or processes that support the other phases and are essential to create or refine the endpoint modality.
- **Creation of the modality:** research that translates the novel concept into the new or refined tangible modality.
- **Preclinical development:** research that refines the modality in animal models to comply with real-world conditions.
- **Early phase clinical trials:** pilot studies, Phase 0, I/II testing in humans to determine safety and efficacy of the modality and whether a definitive clinical trial is warranted.

Applicants for a Translational Research Grant will be required to classify their proposed project according to the TRWG framework. First, they will need to specify which clinical modality their proposed project addresses: risk assessment or interventional. If risk assessment, they will then need to select whether the modality is biospecimen-based and/or image-based; if Interventional, then whether it deals with drug or biologic agents, immune response modifiers, interventional devices, and/or life-style alterations. And finally, the development phase that is addressed in their proposed project: creation of supporting tools, creation of the modality, preclinical development, and/or early stage clinical testing in humans.

Applicants will need to describe the “translational bridge” of their proposed project, including the scientific discovery to be translated and its readiness for next steps, plans for applying the discovery, the practical outcome of the proposed project, solutions to translational barriers, and the potential individual or population-level impact. Given its importance in driving the translational process, cross-disciplinary collaborations should be identified where there is a benefit to the integration of different skill sets. These can include, for example, plans for sharing research materials, methodologies/ technologies, animal models, or human samples.

Milestones/deliverables along the pathway, from the present level of research knowledge to the practical application, will need to be specified. Reliable and quantifiable indicators of progress must be identified, and not the simple completion of tasks. Examples of key milestones might include, but are not limited to, the clinical validation of risk factors that predict pancreatic ductal adenocarcinoma in individuals with diabetes mellitus in a small retrospective study; development of a validated pharmacodynamic assay that reproducibly demonstrates a small molecule inhibitor alters target activity; demonstration that an agent elicits the desired immunological response in pilot clinical trials; or completion of preclinical studies to determine optimum combinations and sequencing of standard of care and new agents in preparation for clinical studies.

Research funded by a Translational Research Grant will typically represent a critical step in a longer-term project that will go beyond the timeframe and budget of this two year grant. Applicants should have a general plan for subsequent steps that will be needed for the translational and clinical exploitation of the proposed study to demonstrate the clinical relevance and potential for improving survival from pancreatic cancer.

BUDGET STIPULATIONS

The Translational Research Grant provides \$300,000 over two years. Funds can be used for direct research expenses related to the proposed project, which may include salary and benefits, research/laboratory supplies, equipment, and publication charges for manuscripts that pertain directly to the funded project. Salary and benefits for the Contact-PI and collaborator(s) can account for up to 20% (\$60,000) of the grant funds; and up to 30% (\$90,000) if a Co-PI is included on the proposed project. Salaries and benefits for postdoctoral or clinical research fellows, technicians, and support staff

are not counted toward this cap; neither are consultant fees. Funds also can be requested for regular communications if a Co-PI is located at a different institution. Up to 10% (\$30,000) of the grant funds may be allocated for equipment.

For institutions that mandate payment of indirect costs, a maximum of 10% (\$27,274) of the total direct costs may be used for this purpose across all institutions. For the purposes of this grant, any general office supplies or individual institutional administrative charges (e.g., telephone, other electronic communication, utilities, IT network, etc.) are considered to be part of indirect and are **not** allowable budget line items. Tuition, professional membership dues, pre-award charges and any other research-related expense not directly related to this project are **not** allowable expenses. In addition, no grant funds may be directed toward salary or benefits of any individuals from a U.S. government institution or for-profit industry, nor for any research expenses related to the project that are incurred by these individuals.

EVALUATION OF APPLICATIONS

Applications for the Translational Research Grant will be reviewed by a Scientific Review Committee comprised of a multidisciplinary panel of scientists respected for their own accomplishments in pancreatic cancer research and/or translational/clinical cancer research, who are viewed as leaders in the field. The Committee will evaluate applications using the below evaluation criteria and will employ an NIH-based scoring system (with 1=Exceptional and 9=Poor).

Readiness: Is there a strong conceptual basis and convincing empirical evidence to support the translational/pre-clinical relevance, scientific validation, and methodological feasibility of the proposed project?

Translational Potential: Does the proposed project address a high priority translational research area that challenges and seeks to shift current clinical practice paradigms by using novel assessment, preventive, or therapeutic approaches or methodologies, instrumentation or intervention? Is the proposed project based on a plan that is well-reasoned, realistic and feasible, and anticipates translational barriers and solutions?

Outcomes: Are short and long-term quantifiable milestones and deliverables clearly specified and reasonable? If successful, will the proposed project inform and facilitate progress towards achieving the 2020 goal of doubling survival for pancreatic cancer?

Project Team: Does the applicant have the appropriate training and expertise to successfully implement the proposed project and overcome obstacles that may arise? Do team members have the needed skills and capabilities, and is the cross-disciplinary expertise included to maximize the translational potential of the proposed project? Is the environment appropriate and conducive to success of the project? Is there sufficient institutional support, equipment and resources available to successfully implement the proposed project?

Budget: Are proposed expenses fully justified and reasonable in relation to the proposed project?

TERMS AND CONDITIONS OF GRANT

Applicants are required to read the Research Grant Terms and Conditions before completing the application form.

II. APPLICATION INSTRUCTIONS

REQUIRED APPLICATION MATERIALS

Applications must be submitted by Noon, Eastern Time on Friday, January 30, 2015, using the proposalCENTRAL website at <https://proposalcentral.altum.com>.

To submit a complete application, applicants need to directly input information into the online application platform as well as upload a number of documents. The following instructions provide details about information that needs to be inputted and the materials that need to be uploaded. The section numbering corresponds with the section number of the online application.

Information to be Entered Directly into proposalCENTRAL	Instructions/proposalCENTRAL Section
Title Page	1
Applicant Information	4
Institution & Contacts	5
Co-PI Information (required if Co-PI included on proposed project)	6
Scientific Abstract	7
Organizational Assurances	8

Templates to be Downloaded, Completed and Uploaded	Instructions/proposalCENTRAL Section
Research Project Proposal Template	9. A.
Other Funding Template	9. B.
Budget and Budget Narrative Template	9. C.
Project Milestones and Timeline Template	9. D.

Non-Template Materials to be Uploaded	Instructions/proposalCENTRAL Section
Applicant's Biographical Sketch	9. E.
Letter of Institutional Support for Applicant	9. F.
Co-PI's Biographical Sketch (required if Co-PI included on proposed project)	9. G.
Letter of Institutional Support for Co-PI (required if Co-PI included on proposed project)	9. H.
Letter of Commitment from Co-PI (required if Co-PI included on proposed project)	9. I.

Materials to be Downloaded, Printed, Signed, Scanned and Uploaded	Instructions/proposalCENTRAL Section
Signed Acknowledgement of Grant Terms and Conditions	9. J.
Application Signature Pages	9. K./12

GETTING STARTED IN proposalCENTRAL

If you are a new user of proposalCENTRAL, follow the "REGISTER" link and complete the registration process. After you register, complete your Professional Profile (second tab from

the left) before starting an application.

If you are already registered with proposalCENTRAL, access the site and log in with your Username and Password. If you have forgotten your password, click on the “Forgot your password?” link. Supply your User ID or e-mail address in the space provided; your password will be sent to you by e-mail.

To start an application, select the “Grant Opportunities” tab (gray tab furthest to the right). A list of applications will be displayed. Find the “Pancreatic Cancer Action Network Translational Research Grant” and click the “Apply Now” link (second to last column) to create your application.

Complete all fields in the application and all templates that are provided. Upload all requested documents in portable document format (PDF). For more information, see the proposalCENTRAL FAQ section, <https://proposalcentral.altum.com/FAQ/FrequentlyAskedQuestions.asp>.

If you have any difficulties registering, logging in, or creating your application, contact proposalCENTRAL Customer Support:

Phone: 1-800-875-2562 or (703) 964-5840

E-mail: pcsupport@altum.com

APPLICATION DETAILS

The following information is required to submit a complete application. Numbers correspond to the application sections found on the left side of the proposalCENTRAL website.

- 1. TITLE PAGE.** Enter the title of the research project directly into the proposalCENTRAL system. The title is limited to no more than 75 characters in length (including spaces). Do not use abbreviations. A project title must be entered and saved before additional sections may be accessed.
- 2. DOWNLOAD TEMPLATES & INSTRUCTIONS.** The Program Guidelines and Application Instructions document, the Grant Terms and Conditions document, and all templates must be downloaded from this page.

The following four templates must be downloaded and completed: Research Project Proposal, Other Funding, Budget and Budget Narrative, and Project Milestones and Timeline.

- Click the “Download” link to save each of the templates to your computer.
- Use your word processing software (e.g., MS Word, WordPerfect) to complete the templates, and then convert the templates to PDF format. You do not need to be connected to the internet or proposalCENTRAL while working on the templates.
- Upload the completed template files to your online application.

The Grant Terms and Conditions must be downloaded and the last page signed by the applicant.

See below on page 8, Section 9 in the Application Instructions for how to complete and upload the templates and the signed, last page of the Grant Terms and Conditions document. This application also requires additional attachments for which a template is not provided (Applicant’s Biographical Sketch; Letter of Institutional Support for Applicant; and if a Co-PI is included on the proposed project: Co-PI’s Biographical Sketch; Letter of Institutional Support for Co-PI; and Letter of Commitment from Co-PI).

- 3. ENABLE OTHER USERS TO ACCESS THIS PROPOSAL.** Optional.

4. **APPLICANT INFORMATION.** Enter information for the applicant directly into proposalCENTRAL system.
5. **INSTITUTION & CONTACTS.** Enter information regarding the lead institution and signing official directly into the proposalCENTRAL system.
6. **CO-PI INFORMATION (required if Co-PI included on proposed project).** If a Co-PI is included on the proposed program, enter his/her institutional affiliation and contact information directly into the proposalCENTRAL system. If there is no Co-PI, disregard this section.
7. **SCIENTIFIC ABSTRACT.** Enter the abstract directly into the proposalCENTRAL system. The abstract should be limited to 3,000 characters (including spaces) and must provide a clear, concise and comprehensive overview of the proposed project. Discuss the relevance of the proposed project to pancreatic cancer, the foundational research that has been completed to justify proposed next steps, the practical application that is proposed, specific aims and activities that are planned, the study design, expected accomplishments by the conclusion of the grant term, and how results will facilitate doubling of survival from pancreatic cancer by 2020. Also, describe the cross-disciplinary skills of the project team and how this skill set will help maximize the translational potential of the proposed project.

NOTE: The proposalCENTRAL system does not lock the scientific abstract field after 3,000 characters have been entered. To ensure that your abstract does not exceed the character limit, before proceeding to the next section click the red “Save” button at the top or bottom of the screen. If the scientific abstract is too long, you will receive an error message at the top of the page.

8. **ORGANIZATIONAL ASSURANCES.** Select the appropriate assurances options for your proposed research and complete the Approved or Pending Date field as appropriate (i.e., mm/dd/yyyy, N/A, or None). The assurances/certifications are made and verified by the signature of the institutional official signing the application. If a grant is awarded, IRB and/or IACUC approval (if applicable) must be submitted in writing to PanCAN’s Research & Scientific Affairs Department.

9. APPLICATION DOCUMENTS.

Formatting Instructions:

- Type size. 12 point Times New Roman for the text, and no smaller than 9 point type for tables and figures, if included.
- Line Spacing. Single-spaced format, and indent to begin new paragraphs.
- Margins. Page margins no less than .75 inches on each side.
- Instructions for inserting tables and figures.
 - Reduce the file size of documents with images by “inserting” the image (as opposed to “cutting” and “pasting”). Save graphical images as a JPG or GIF file. Insert the image into the document by selecting “Insert – Picture – From File” from the MS Word menu.
 - Insert only JPG or GIF graphic files as images in your Word document.
 - Do not insert Quick Time or TIFF objects into your document.
 - Anchor the images that are embedded in the document.
 - Once the inserted image is anchored, format the text to wrap around the image.
 - Do not edit images in Word. Use a graphics program.

- Do not embed images in tables, text boxes, and other form elements.
- Do not add annotations over the images in Word. Add annotations to the images itself in a graphics program.

Using the templates where provided, prepare and upload the following documents into your application in portable document format (PDF):

A. Research Project Proposal. *Complete on the template available from the proposalCENTRAL website. (Refer above on page 7, Section 2 in the Application Instructions for details.) The information must be presented in this order:*

- I. Contents Page.** Complete the Table of Contents by indicating the appropriate page numbers for each section. The Table of Contents page should not exceed 1 page.
- II. Translational Research Classification.** Using the framework developed by the Translational Research Working Group, select the (A) Clinical Modality; (B) Pathway; and (C) Developmental Phase for the proposed project. *(Refer above on pages 3-4 in the Program Guidelines for details about the classification.)*
- III. Lay Abstract.** The lay abstract should use language suitable for a non-scientific audience and provide a clear, concise and comprehensive overview of the proposed work. Summarize the scientific discovery that will be translated, plans for applying the discovery, the practical outcome of the proposed project, solutions to potential barriers, and the potential impact on pancreatic cancer, including how results will contribute to the goal of doubling survival from pancreatic cancer by the year 2020.
- IV. Credentialing Research.** Maximum 2 pages, including figures and tables. Summarize the foundational research that supports the proposed project. The narrative must be presented in the following order and summarize the empirical basis for the: (A) Scientific Validation of the discovery that underlies the proposed modality; (B) the Clinical Need for the proposed modality; and (C) its Methodological Feasibility. Include evidence that specifically addresses and justifies the approach that is presented in the proposed project. Include foundational research completed by PI(s).
- V. Proposed Project.** Maximum 8 pages, including figures and tables. The narrative must be presented in this order: (A) Specific Project Aims; (B) Research Design and Methods, including a description of the pancreatic cancer/pre-cancer resources that will be used; (C) Potential Implementation Problems, Solutions and Alternative Strategies; (D) Population Segment that will be targeted to benefit from the proposed modality, and expected timeframe for application in humans; (E) Expected Accomplishments by the conclusion of the proposed project and the measure(s) of effectiveness that will be used to assess achievement of goal(s); (F) How the Proposed Project will Facilitate Achievement of the Goal to Double Survival from Pancreatic Cancer by the Year 2020; and (G) Critical Next Steps, if the longer-term project exceeds the budget or timelines of this funding opportunity.
- VI. Facilities.** Maximum 2 pages. Describe the research facilities, resources, and equipment that are available to the applicant and Co-PI, if included, to help ensure successful implementation of the proposed project. Identify any resources that are expected to be contributed by nonacademic partners.
- VII. References.** Maximum 3 pages. List key publications that support the proposed project, including those (co)authored by the applicant and/or Co-PI, if included. References must be

listed as FULL CITATIONS. Each citation must include names of all authors, publication title, journal or book title, volume number, page numbers, and year of publication.

B. Other Funding. *Complete on the template available from the proposalCENTRAL website. (Refer above on page 7, Section 2 in the Application Instructions for details.)* List all existing support (institutional, federal, etc.) that has been secured and will be used by the applicant during the term of this grant (07/01/2015 – 6/31/2017), or is pending, regardless of the project focus and whether or not the applicant is the Principal Investigator. Repeat this information for the Co-PI, if included. For each, specify:

- Whether Funding is Secured or Pending
- Name of Principal Investigator
- Funding Organization
- Type of Grant/Funding
- Project Title
- Grant Term (Start/End Date)
- Amount of Funding
- % Effort of Contact-PI (and Co-PI, if included)
- List of Specific Aims

C. Budget and Budget Narrative. *Complete on the template available from the proposalCENTRAL website. (Refer above on page 7, Section 2 in the Application Instructions for details.)* Specify the percent time that the applicant and Co-PI, if included, will plan to allocate annually to the proposed project, if funded. The Translational Research Grant provides \$300,000 over two years. Funds can be used for direct research expenses, including salary and benefits, research/laboratory supplies, equipment, and publication charges for manuscripts that pertain directly to the proposed project. Salary and benefits for the applicant and collaborator(s) can account for up to 20% (\$60,000) of the grant funds; and up to 30% (\$90,000) if a Co-PI is included on the proposed project. Salaries and benefits for postdoctoral or clinical research fellows, technicians, and support staff are not counted toward this cap; neither are consultant fees. Funds also can be requested for regular communications if a Co-PI is located at a different institution. Up to 10% (\$30,000) of the grant may be allocated for equipment.

For institutions that mandate payment of indirect costs, a maximum of 10% (\$27,274) of the total direct costs may be used for this purpose across all institutions. For the purposes of this grant, any general office supplies or individual institutional administrative charges (e.g., telephone, other electronic communication, utilities, IT network, etc.) are considered to be part of indirect and are **not** allowable budget line items. Tuition, professional membership dues, pre-award charges and any other research-related expense not directly related to this project are **not** allowable expenses. In addition, no grant funds may be directed toward salary or benefits of any individuals from a U.S. government institution or for-profit industry, nor for any research expenses related to the project that are incurred by these individuals.

D. Project Milestones and Timeline. Complete Column A on the Project Milestones and Timeline template that is available from the proposalCENTRAL website. *(Refer above on page 7, Section 2 in the Application Instructions for details.)* The Project Milestones and Timeline Template is meant to list the various milestones and deliverables necessary to complete your research aims

and the estimated time it will take to complete each. Please list your specific aims for the proposed project at the top of the template. Underneath each time period, identify the milestones and deliverables that will be accomplished in that time period. For each milestone and deliverable, note the corresponding aim in parentheses. Should you receive a grant, this template will be used as part of your progress reports.

- E. Applicant's Biographical Sketch.** The biographical sketch must be in English. The NIH Biographical Sketch Form [PHS 398/2590 (Rev. 06/09)] is an acceptable format. The biographical sketch may not exceed four pages.
- F. Letter of Institutional Support for Applicant.** A Letter of Institutional Support for the applicant is required. The Letter must be written on letterhead by the department head, dean or other senior member of the institution on behalf of the applicant and should be addressed to the Scientific Review Committee. It should explain the applicant's relationship with the institution, and the nature and extent of support for the proposed research that is available from the institution, including laboratory space, financial support, and other resources.
- G. Co-PI's Biographical Sketch (required if Co-PI included on proposed project).** The biographical sketch must be in English. The NIH Biographical Sketch Form [PHS 398/2590 (Rev. 06/09)] is an acceptable format. The biographical sketch may not exceed four pages.
- H. Letter of Institutional Support for Co-PI (required if Co-PI included on proposed project).** The Letter of Institutional Support must be written on letterhead by the department head, dean or other senior member of the Co-PI's institution. It should be addressed to the Scientific Review Committee and explain the Co-PI's relationship with the institution, and the nature and extent of support for the proposed research that is available from the institution, including laboratory space, financial support, and other resources.
- I. Letter of Commitment from Co-PI (required if Co-PI included on proposed project).** This is not a letter of recommendation but rather confirms the scope of the Co-PI's involvement, how his/her qualifications and expertise complement the Contact-PI's and will benefit the project, his or her percent effort on the proposed project, and plans for communication and coordination with the Contact-PI. The Letter should be addressed to the Scientific Review Committee.
- J. Signed Acknowledgment of Grant Terms and Conditions Document.** To ensure the applicant is informed of the terms and conditions of the grant, a copy of the Grant Terms and Conditions must be downloaded from the proposalCENTRAL site. Applicants must remove the final page of the Grant Terms and Conditions document and sign and date it, acknowledging that they have received and read the document. The terms and conditions of this grant may be modified or amended by PanCAN prior to execution of the Grant Agreement. *A scanned copy of the signed final page must be uploaded* to your online application in the section for attaching files.
- K. Application Signature Pages.** To ensure that the applicant and institution have approved the application, applicants must print the Signature Pages, as described in section 12 below, and obtain all required signatures. The **signed Signature Pages** (with original signatures from the applicant and institution's signing official) must then be *scanned and uploaded into the online application*.

Uploading the attachments into your application. Once you have converted your attachments to PDF files, the next step is to upload the files to your online application.

- Make certain that the converted PDF files are closed on your computer.

- Open your application and go to the section for attaching files.
- Enter your own description of the file in the “Describe Attachment” field.
- Select the appropriate type of attachment from the drop-down list. *NOTE: After selecting attachment type, the screen will show the file types (e.g., PDF, .doc) that are allowed for that type of attachment. Only PDF attachments are permitted for this application submission.*
- Click on the “Browse” button to select the file from your computer.
 - ♦ A “choose file” dialog box opens for you to search for the template file on your computer’s hard disk or local area network.
 - ♦ Select the file and click “Open.”
 - ♦ The file location and name will display in the window adjacent to the “Browse” button.
- Click on the “Upload Attachment” button. You will get a confirmation message on your screen that the file was uploaded successfully. You also will see that your file is now listed in the “Uploaded Attachment” section of the screen. Two links are available in each row of an uploaded attachment: DEL and SHOW. “DEL” allows you to delete the file, if necessary, and “SHOW” opens the uploaded file. **Open and review your uploaded files.**

In the section for attachments, all the required attachments are listed in the middle of the screen, just below where you upload your files. This list of required attachments helps you track completion and uploading of your required attachments. Once you upload a required attachment, that attachment type will be removed from the required list and will be displayed in the "Current list of uploaded attachments."

If you wish to modify the attached file, make the revisions to your **original** file on your computer (off-line), convert the file to PDF, and use the same process above to attach the newly revised file. **Delete any previously submitted versions of the file before submitting your application.**

SUBMITTING COMPLETE APPLICATION

- 10. PI DATA SHEET.** This is an automatically populated data sheet based on the applicant’s proposalCENTRAL profile. Information for gender, race, and ethnicity must be provided. If fields are not populated, go to Section 4, Applicant, and select the “Edit Professional Profile” tab in the center of the screen. The applicant must then go to the column on the left side of the screen, select “4) Personal Data for Application” and enter his/her gender, race, and ethnicity. The Grant Selection Committee does not receive this information.
- 11. VALIDATE.** Validate the application on proposalCENTRAL. This is an essential step. ‘Validate’ checks for required data and required attachments. You will not be able to submit the application if all the required data and attachments have not been provided.
- 12. SIGNATURE PAGES AND PRINT APPLICATION.** After completing sections 1, 4, 5, 7 and 8 (and section 6, if a Co-PI is included on proposed project) of the electronic application (these sections also correspond to the sections of the Applications Instructions), you may print the Signature Pages. Use the “Print Signature Pages” print button. Click this button to print the Signature Pages for signatures.

Note: Data that you entered in the immediately above referenced sections of the online application are automatically included in the Signature Pages. If information is missing in the Signature Pages,

it could be because you have not entered the information in one of the proposal sections OR the information is not required for this grant program. If the institution's Employer Identification Number (EIN) is not completed on the Signature Pages, please ask your institution to provide that information in their proposalCENTRAL profile.

The print option "Print Signature Pages" prints the Signature Pages, Application Contacts, and Scientific Abstract. If your institution wishes to review the application in its entirety, select the "Print Signatures Pages and Attached PDF Files" option.

Obtain required signatures. PanCAN requires that the completed application and Signature Pages with original signatures of the applicant and institutional signing official be uploaded into the Application Documents.

Upload the signed Signature Pages into the application in the "9) Application Documents" section. Do not upload the Application Contacts and Scientific Abstract pages with the Signature Pages.

13. SUBMIT. After successfully passing the validate check and printing your documents, click the 'Submit' link. An e-mail will be sent to you confirming your submission.

Once your application is submitted, you may view it by accessing the 'Submitted' link under the Manage Proposals tab. The status column will show "Submitted" and the date submitted. You may need to refresh your browser screen after submitting the application to see the updated status.

CHANGES TO YOUR APPLICATION

Withdrawal of Application. Please advise PanCAN promptly, in writing, should you decide to withdraw your application for any reason. Your letter (or e-mail) should include your name, the title of the proposal, and the reason for withdrawal.

Change of Address. Notify PanCAN in writing of any changes of address, e-mail or phone number, following the submission of an application. Include your name and the application number.

Change of Institution or Position. If you change your institution or professional position, contact PanCAN to determine whether your application is still eligible for review.

INQUIRIES

Inquiries or technical issues regarding proposalCENTRAL and the online application process should be directed to customer support at (703) 964-5840, or toll free at 1 (800) 875-2562, or by e-mail at pcsupport@altum.com.

Inquiries about the grant guidelines and application materials should be directed to PanCAN at grants@pancan.org or (310) 725-0025. Contact Person: Rhonda Aizenberg, PhD, Director, Grants Program.