2017 PANCREATIC CANCER ACTION NETWORK

TRANSLATIONAL RESEARCH GRANT

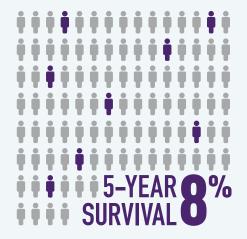Guidelines and Application Instructions

PANCREATIC CANCER ACTION NETWORK

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PANCREATIC CANCER HAS THE LOWEST FIVE-YEAR RELATIVE SURVIVAL RATE OF ALL MAJOR CANCERS

5-YEAR SURVIVAL 8%

ADVANCE RESEARCH. SUPPORT PATIENTS. CREATE HOPE.

Please direct questions to:

Pancreatic Cancer Action Network – Research Grants Department
1500 Rosecrans Avenue, Suite 200 | Manhattan Beach, CA 90266
Office (310) 725-0025 | grants@pancan.org

I. GUIDELINES

BACKGROUND

The Pancreatic Cancer Action Network announced a bold initiative in February 2011, a vision of progress aimed at bettering the odds for everyone affected by pancreatic cancer: ***Double survival by the year 2020.*** **Wage Hope** is our rallying cry, our relentless call to action to accelerate progress in the fight against pancreatic cancer. We need you as our partners in the fight!

The Pancreatic Cancer Action Network has a competitive Grants Program that funds promising and meritorious research on pancreatic cancer. The organization's grantmaking strategy recognizes the need to build the pipeline of researchers dedicated to studying pancreatic cancer and the urgency to accelerate scientific and medical breakthroughs that benefit patients. Early career grants are awarded to attract new researchers to the field of pancreatic cancer, and translational and clinical grants support research that is well positioned for next steps and that has the potential to drive improvements in clinical practice and patient outcomes.

The adoption of the 2020 goal prompted an in-depth evaluation of the organization's programs to ensure that they are effectively aligned with the goal. Since then, several new grant mechanisms have been introduced to speed discoveries that will contribute to the goal. In 2014, the Pancreatic Cancer Action Network launched a grant mechanism to fund translational research. Since then, 13 translational research projects have been funded through these grants.

The **2017 TRANSLATIONAL RESEARCH GRANT** will fund high priority pancreatic cancer research that is poised for important translational next steps in order to help move discovery to application in patients. The grant provides $300,000 over two years for a translational research project that has as its endpoint the development of a pancreatic cancer assessment, prevention or treatment modality. For purposes of this grant, translational research is defined according to the framework conceived by the Translational Research Working Group, created under the auspices of the U.S. National Cancer Advisory Board. Specifically, these grants fund research that ***follows*** fundamental discovery, all the way through phase 1/2 clinical trials. (See below for additional details.)

To be eligible for a Translational Research Grant, 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 <u>not</u> eligible for funding through this grant mechanism.

The type of project that will qualify for funding will typically benefit from the inclusion of cross-disciplinary expertise. Therefore, applications can include one contact principal investigator (PI) or a contact PI and a co-PI. If there are two PIs, they should include a basic scientist and a clinician. It is anticipated that five 2017 Translational Research Grants will be awarded.

The deadline for submitting an application for a Translational Research Grant is Thursday, December 1, 2016, at noon Eastern Standard Time. Funding decisions will be available May 2017. The grant term begins July 1, 2017.

Applicant eligibility

- The contact principal investigator (contact PI) must be affiliated with an academic, medical or research institution **within the United States.**

- There is no citizenship requirements, but the contact PI who is not a U.S. citizen must have a visa status that provides sufficient time to complete the project and the grant term within the U.S.

- Given its importance in driving the translational process, the project team should involve cross-disciplinary skills. Projects supported by these grants will especially benefit from collaborations between basic and clinical scientists.

- It is optional but encouraged to include a co-PI. If the contact PI is a basic scientist, the co-PI must be a clinician/clinical scientist. Conversely, if the contact PI is a clinician/clinical scientist, the co-PI must be a basic researcher.

- The co-PI can be affiliated with any academic, medical or research institution in the world.

- Each PI must be an independent researcher with a doctoral degree (including PhD, MD, DO, PharmD or equivalent) in the biomedical sciences or in a field applicable to health science research.

- Researchers can be a contact PI on one application and may be identified as a co-PI on a second application.

- Employees or subcontractors of a government or for-profit entity are not eligible to be a PI or to receive funds from the grant, but can be included as a collaborator or project investigator.

One contact PI and the option of one co-PI who are independent investigators and hold doctoral degrees

Contact PI must be affiliated with a U.S. academic, medical or research institution

Co-PI, if included, can be affiliated with any academic, medical or research intitution in the world

Research team with multidisciplinary experience

Project eligibility

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. (Additional information can be found in the TRWG report, *Transforming Translation: Harnessing Discovery for Patient and Public Benefit*, published in June 2007, and a series of seven articles on the TRWG pathways 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 fundamental laboratory, clinical or population-based discoveries 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. On a research discovery continuum, the TRWG focus was on "early translational research" and specifically on the phases of research that **follow** scientific validation of a discovery up until definitive, late-stage trials.

Consistent with the TRWG framework, the Translational Research Grant will support research that follows fundamental discovery, all the way through phase 1/2 clinical trials. The proposed project cannot consist of fundamental discovery or basic science research. **To be eligible for consideration, the scientific validation, clinical need and feasibility of developing the proposed clinical modality must already be established and will be required to be presented as part of the application process.**

Projects that are funded by the Translational Research Grant will leverage existing knowledge and experience. When assessing the readiness of a project for this grant mechanism, applicants should evaluate whether there is a strong foundation for the proposed research. This includes, but is not limited to:

• Previous studies in pancreatic cancer mouse/animal models or significant work in cell culture.

• Validation of targets or hits from chemical, genomic or genetic screens that go beyond the initial discovery.

• Credentialing or foundational research in other cancer models that has justifiable promise for pancreatic cancer and where a strong rationale can be provided of its relevance to this disease.

The below figure illustrates the TRWG framework. This framework 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	No	Credentialing	I. Biospecimen-based	II. Image-based	I. Agents (drugs & biologics)	II. Immune response modifiers	III. Interventive devices	IV. Lifestyle alterations	
	✔	Creation of modality							
	✔	Preclinical development							
	✔	Clinical trials							

The TRWG framework includes two clinical modality endpoints: risk assessment and interventive. The risk assessment modality involves research to characterize the cancer-related health status of an individual, and includes pancreatic cancer screening, detection, diagnosis, prognosis or treatment response assessment. The interventive modality involves research to change the cancer-related health status of an individual, and deals with pancreatic cancer prevention or treatment.

The risk assessment modality has two pathways; the interventive modality has four pathways. Each pathway consists of five developmental phases along the research discovery continuum. (See *Clinical Cancer Research* 14, 5664-5671, 2008 for an overview of the TRWG pathways.)

Two Risk Assessment Modality Pathways

I. **Biospecimen-based assays:** involves 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:** includes, for example, nanotechnology, fluorescence, MRI and PET to analyze tissue noninvasively for the detection, diagnosis or prognosis of pancreatic cancer and pre-cancer or to assess treatment response.

Four Interventive Modality Pathways

I. **Drug or biologic agents:** therapeutic or preventive agents (e.g., novel chemotherapeutic compounds) that can be used to treat pancreatic cancer or prevent the disease in high-risk individuals.

II. **Immune response modifiers:** agents (e.g., vaccines and cytokines) that modify the immune system to treat or prevent pancreatic cancer.

III. **Interventive devices:** devices designed for prevention or local ablation of pancreatic cancer (e.g., novel surgical techniques and radiotherapy image-guided interventions).

IV. **Lifestyle alterations:** behavioral, environmental and physiological interventions (e.g., modifying risk-related behaviors or environmental exposures) that are distinct from agents, immune modifiers and devices.

Five Developmental Phases of Each Pathway

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

II. **Development of supporting tools:** research that develops collateral tools, techniques or processes that support the other phases and is essential to create or refine the endpoint modality.

III. **Creation of the modality:** research that translates the novel concept into the new or refined tangible modality.

IV. **Preclinical development:** research that refines the modality in animal models to comply with real-world conditions and to support clinical trials.

V. **Early phase clinical trials:** pilot studies or phase 0, 1/2 testing in humans to determine whether a definitive, more robust clinical trial is warranted.

Applicants will be required to classify their proposed project according to the TRWG framework. First, they will need to specify the clinical modality that their proposed project addresses: risk assessment, interventive-preventive or interventive-treatment. If risk assessment, they will then need to select whether the modality is biospecimen- and/or image-based; if interventive (preventive or treatment), they will need to identify whether it deals with drug or biologic agents, immune response modifiers, interventive devices and/or lifestyle alterations. And finally, the developmental phase of the proposed project needs to be specified and explained: 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. Specifically, this includes discussing the scientific discovery that will be translated, its readiness for next steps, plans for applying the discovery, potential barriers and solutions and the expected outcome of the project.

The following are examples of projects that could be ready for a Translational Research Grant.

NOTE: these are examples and applications are not restricted to projects that fall within these scenarios.

• A retrospective study of risk factors that predict pancreatic cancer in individuals with diabetes mellitus.

• Optimization and analysis of small molecule modifiers of a validated target.

- Studies on drug resistance to standard-of-care or targeted therapies in a well-established experimental system or as part of a clinical trial.

- Preclinical or early phase clinical studies on the immunological response to treatment with immune modifiers.

- Preclinical studies to determine optimum combination and sequencing of standard-of-care and new agents in preparation for a clinical trial.

- Early human testing of drug delivery strategies that target the stroma or tumor.

- Preclinical or early phase trials to determine the utility of selected assays, markers and/or imaging tests to help guide treatment assignment or assess therapeutic response.

Milestones and deliverables will need to be established and relevant measure(s) of effectiveness identified for the grant period. Funded projects will typically represent a critical step in a longer term project that will go beyond the timeframe and budget of this two year grant. Therefore, applicants will need to describe a general plan for subsequent steps along the developmental pathway that would result in a definitive clinical trial, if warranted, and a change in clinical practice that would contribute to the 2020 goal of doubling pancreatic cancer survival.

Use of funds

The Translational Research Grant provides $300,000 over two years. Funds can be used for salaries and benefits, laboratory supplies, equipment (maximum of 10 percent of total grant), subject trial costs and publication charges for manuscripts that pertain directly to the proposed project. Expenses for regular communications can be included if a co-PI is located at a different institution.

For institutions that mandate payment of indirect costs, a maximum of 10 percent of the total grant may be used for this purpose across all institutions. 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 expenses and are not allowable budget line items.

Tuition, professional membership dues, pre-award charges and any other research-related expenses not directly related to the 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 or for-profit entity, or for any research expenses related to the project that are incurred by these individuals.

Community for Progress

The Pancreatic Cancer Action Network is building a robust and collaborative research community, a Community for Progress, dedicated to changing the course of history for pancreatic cancer. Grant recipients will have opportunities to interface with the organization and engage with the broader pancreatic cancer community throughout the grant term. When invited, they are required to attend the organization's Annual Scientific Meeting, which brings together grantees, advisors, industry representatives and other guests. The next meeting is scheduled for August 17-20, 2017, in San Diego, CA. Applicants for a Translational Research Grant should plan to save these dates in the event their proposed project is selected for funding. The annual meeting includes scientific sessions in which grantees report on their funded research and receive input from advisors, special issue sessions, networking sessions and opportunities to forge collaborations. Travel support to attend the meeting is provided separate from the grant by the Pancreatic Cancer Action Network.

EVALUATION OF APPLICATIONS

Translational Research Grants will be awarded using a competitive, rigorous peer review process. Applications will be evaluated by a Scientific Review Committee composed of scientists who are respected for their accomplishments in pancreatic cancer, translational research and clinical trials. A pancreatic cancer research advocate will also serve on the committee to represent the collective patient perspective.

The Committee will consider the following criteria when reviewing applications:

Readiness

- Is there a strong scientific rationale to the proposed project?
- Have the appropriate foundational studies been performed to demonstrate and support the translational/preclinical relevance, scientific validation and methodological feasibility of the proposed project?
- If the foundational research applies to another cancer model, is there a strong rationale to justify the application to pancreatic cancer?
- Is the proposed research ready and a good match for funding by this grant mechanism?

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?
- Have possible barriers been anticipated and are solutions and alternative strategies proposed?
- Are all the needed resources, including drugs and reagents, readily available?
- Are proposed expenses fully justified and reasonable in relation to the proposed project?

Outcomes

- Are quantifiable milestones and deliverables clearly specified and reasonable?
- Is there a plan to measure project outcomes and is it reasonable and appropriate?

Project team

- Does the PI(s) have the appropriate training, expertise and track record of accomplishments to successfully implement the proposed project and overcome obstacles that may arise?
- Do the project team members have the needed cross-disciplinary skills and capabilities to successfully complete the project, and is there evidence that they can successfully work together?
- Has the necessary infrastructure for the project been identified and is the environment appropriate and conducive to the success of the project?
- If the project involves multiple institutions, is the communication plan sufficient?

Alignment with organizational priorities

- Is there strong alignment between the proposed project and the priorities of the Pancreatic Cancer Action Network?
- If funded, will the project positively contribute to the organization's overall grants portfolio?
- If successful, will the proposed project inform and contribute to the 2020 goal of doubling pancreatic cancer survival?

II. APPLICATION INSTRUCTIONS

APPLICATION PROCEDURES

Required application materials

Applications must be submitted by **noon Eastern Standard Time on Thursday, December 1, 2016**, using the proposalCENTRAL website at https://proposalcentral.altum.com.

To submit a complete application, the contact PI (applicant) needs to enter information directly into the online application platform as well as upload a number of documents. The following instructions provide details about information that needs to be entered and the materials that need to be uploaded. The section numbering in the table below corresponds to the application sections found on the left side of the proposalCENTRAL application Web page and to the sections that follow in the Application Instructions.

Information to be entered directly into proposalCENTRAL	Instructions/ proposalCENTRAL Section
Title Page	1
Contact PI (Applicant) Information	4
Institution and Contacts	5
Project Team	6
Scientific Abstract	7
Organizational Assurances	8
Templates to be downloaded, completed and uploaded	
Research Project Proposal Template	9.A
Other Financial Support Template	9.B
Budget Template	9.C
Project Milestones and Timeline Template	9.D
Non-template materials to be uploaded	
Biographical Sketch of Contact PI	9.E
Biographical Sketch of Co-PI (required if co-PI included on proposed project)	9.F
Letter of Commitment from Co-PI (required if co-PI included on proposed project)	9.G
Letter(s) of Institutional Support (required for contact PI and also for co-PI, if latter included in the proposed project)	9.H
Letter(s) of Commitment from Collaborator(s) (including those supplying resources)	9.I
Appendix (if needed)	9.J
Materials to be downloaded, printed, signed, scanned and uploaded	
Signed Acknowledgement of Grant Agreement Terms and Conditions	9.K
Application Signature Pages	9.L/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 (green tab, 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 email address in the space provided; your password will be sent to you by email.

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.

*Important note: To ensure your PDF files upload in their entirety, please avoid: replacing files multiple times, using files that were once password-protected or encrypted and combining multiple scanned documents or files into one PDF. Review your full application before submitting to check that all pages of your PDF files are displaying properly.

> *If you have difficulty registering, logging in or creating your application, contact proposalCENTRAL Customer Support. Phone: (800) 875-2562 or (703) 964-5840; Email: pcsupport@altum.com.*

COMPLETING THE APPLICATION

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

1. **Title Page.** Enter the title of the proposed 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. Also complete the other required (*) items on this page.

2. **Download Template and Instructions.** The Guidelines and Application Instructions document, the Grant Agreement Terms and Conditions and all templates must be downloaded from this page.

   An Application Packet Checklist is also available to download from this page. The checklist does not need to be uploaded to the application but provides a guide for all materials that need to be submitted.

   The following four templates must be downloaded and completed: Research Project Proposal Template, Other Financial Support Template, Budget Template and Project Milestones and Timeline Template.

   • Click the "Download" link to save each of the templates to your computer.
   • Use your spreadsheet software (e.g., MS Excel) to complete the Budget and Project Milestones and Timeline Templates and your word-processing software (e.g., MS Word) to complete the other 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 Agreement Terms and Conditions must be downloaded and the last page signed by the contact PI and signing official from the sponsoring institution.

See below on page 9, Section 9 in the Application Instructions for how to complete and upload the templates and the signed last page of the Grant Agreement Terms and Conditions.

The following additional attachments, for which a template is not provided, are also required: Biographical Sketch of Contact PI and Letter of Institutional Support for Contact PI. If a co-PI is included on the proposed project, also required are: Biographical Sketch of Co-PI, Letter of Commitment from Co-PI and Letter of Institutional Support for Co-PI. If a collaborator is included on the proposed project, including one that is supplying resources, a Letter of Commitment from Collaborator is required from each collaborator.

3. **Enable Other Users to Access this Proposal.** Optional.

4. **Contact PI (Applicant) Information.** Enter information for the contact PI directly into proposalCENTRAL system. The contact PI is required to update his/her Professional Profile, including contact information, other support and publications.

5. **Institution and Contacts.** Enter information for the contact PI's institution, post-award contact person and the designated signing official directly into the proposalCENTRAL system.

6. **Project Team.** Enter contact information for the co-PI, if included on the proposed project, directly into proposalCENTRAL. Also enter contact information for investigators and other key personnel that will compose the project team. Project members should be separately listed for each participating institution beginning with the most senior role.

7. **Scientific Abstract.** Enter the abstract directly into the proposalCENTRAL system. The abstract should be limited to 3,000 characters (including spaces) and must be concise and comprehensive. Describe 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 planned, the specific aims, activities and study design, expected accomplishments by the conclusion of the grant term and how results will contribute to the goal of doubling pancreatic cancer survival by the year 2020. Also, discuss the cross-disciplinary skills of the project team and how this skillset 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, click the red "Save" button at the top or bottom of the screen before proceeding to the next section. If the scientific abstract is too long, you will receive an error message at the top of the page.

   From the list provided, select the primary and, if applicable, secondary Common Scientific Outline code that best describes the proposed project. For additional details about these research categories, see https://www. icrpartnership.org/CSO.cfm.

8. **Organizational Assurances.** Select the appropriate assurances options for your proposed research and complete the Approved or Pending Date field. If a grant is awarded, you will be required to submit the regulatory and compliance documents to the Pancreatic Cancer Action Network.

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 or other images.

   • **Spacing.** Single-spaced format, and indent to begin new paragraphs.

   • **Margins.** No less than 0.75 inch on each side.

- **Instructions for inserting images.**

  - 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.

  - Do not insert Quick Time or TIFF objects into your document; only JPG or GIF graphic files should be used.

  - 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 themselves 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 in the template available from the proposalCENTRAL website. (Refer above on page 8, Section 2 in the Application Instructions for details.) The information must be presented in this order:

I. **Contents.** Complete the table of contents by indicating the appropriate page numbers for each section.

II. **Translational Research Classification.** Classify the proposed project using the framework developed by the TRWG. Complete Sections A, B.1 or B.2, and C. If there are multiple responses for any item, select the top choice. (Refer above on pages 3-4 in the Guidelines for details about the classification.)

   A. Clinical Modality
   (Risk Assessment, Inverventive-Preventive or Interventive-Treatment)

   B.1 Risk Assessment Pathway
   (Biospecimen-Based Assay or Image-Based Technique)

   B.2 Interventive (Preventive or Treatment) Pathway
   (Drug or Biologic Agent, Immune Response Modifiers, Interventive Devices or Lifestyle Alterations)

   C. Developmental Phase
   (Development of Support Tools, Creation of Modality, Preclinical Development or Early Phase Clinical Trials)

III. **Public Abstract.** This abstract, limited to 3,000 characters (including spaces), should be different from the scientific abstract described in page 9, section 7, in the Application Instructions. This will be used to communicate your project to the public, if funded. It should be geared toward a lay audience and provide specific information and insights about your project to share with donors, patients and other stakeholders. Avoid abbreviations. Describe the overall objective of the project, the scientific discovery that will be translated, plans for applying the discovery, including aims, methods and samples; how results will benefit patients and contribute to the 2020 goal of doubling pancreatic cancer survival; and plans for measuring and evaluating progress. Do not include proprietary/confidential information. The content of this summary may be edited or otherwise modified for formatting and style, with prior approval of the applicant, if funded.

IV. Credentialing Research. Maximum 2 pages, including tables, figures or other images. Summarize the foundational research and empirical evidence that support the proposed project. Include background research that specifically addresses and justifies the approach that is presented in the proposed project, the clinical need for the modality and its methodological feasibility. Include foundational research completed by the PI(s). Importantly, if this research applies to another cancer model, explain the rationale for its relevance to pancreatic cancer and why it is a promising application worthy of funding by a Translational Research Grant. The narrative must be presented in the order specified and include these subheadings:

    A. Scientific Validation   B. Clinical Need   C. Methodological Feasibility

V. Proposed Project. Maximum 8 pages, including tables, figures and other images. Provide details of the proposed project, including the aims and research methods, potential problems and solutions, expected accomplishments and plans for assessing whether they been achieved, how the proposed project will contribute to the goal of doubling pancreatic cancer survival by the year 2020 and next steps that go beyond the timeframe and budget of the requested grant. If the project includes a clinical component, describe the clinical protocol and number of subjects that will be enrolled during the two year grant period. The information must be presented in the order specified and include these subheadings:

A. Specific Aims	D. Expected Accomplishments
B. Research Design and Methods	E. Contribution to 2020 Goal
C. Potential Implementation Problems, Solutions and Alternative Strategies	F. Next Steps
	G. Cell Lines Used and Authentications

VI. Project Team. Maximum 2 pages. To be completed if the project includes a co-PI. Describe the benefits and value-added activities the collaboration between the contact PI and co-PI brings to the proposed project. Discuss the plan for communicating and coordinating project activities. Information should be presented in the order specified and include these subheadings:

    A. Collaboration Benefits   B. Communication/Coordination Plans

VII. Facilities. Maximum 2 pages. Describe the research facilities, resources and equipment that are available to the contact PI that will allow successful implementation of the proposed project. If a co-PI is included on the project, also describe the facilities and resources that his/her institution will contribute to the project. Identify any resources that are expected to be contributed by nonacademic partners. Information should be presented in the order specified and include these subheadings:

A. Facilities – Contact PI	C. Other Resources – Nonacademic Partners
B. Facilities – Co-PI	

VIII. References. Include publications on the foundational research authored by the contact PI and, if included, the co-PI. List references as full citations, including names of all authors, publication title, journal or book title, volume number, page numbers and year of publication.

B. Other Financial Support. Complete on the template available from the proposalCENTRAL application website. (Refer above on page 8, Section 2 in the Application Instructions for details.) Provide details for all existing financial support (institutional, federal, etc.) that has been secured and will be used in whole or in part by the contact PI during the term of this grant (7/1/17 – 6/30/19), including funding for which he/she is not the principal investigator. This may include support for different projects. For each grant or funding source, please provide: Name of Principal Investigator, Funding Organization, Type of Grant/Funding, Title of Project, Grant Term, Amount of Funding, Percent Effort of Contact PI and List of Specific Aims as Stated in Grant Proposal (summaries will not be accepted). If funding has been secured for one or more of the aims included in the

proposed project, explain how the Translational Research Grant will expand on this funding, but not constitute an overlap. Also provide details for all pending support that, if secured, will be used in whole or in part by the contact PI during the term of this grant. If a co-PI is included on the proposed project, also list their existing and pending support for the time period covered by this grant term. Information should be presented in the order specified and include these subheadings:

I. Financial Support for Contact PI (complete subsections A-C)

II. Financial Support for Co-PI (complete subsections A-C, if appropriate)

C. **Budget.** Complete on the template available from the proposalCENTRAL application website. (Refer above on page 8, Section 2 in the Application Instructions for details.) The Translational Research Grant provides $300,000 over two years. The budget should be presented for each year of the grant term. Specify the percent time that the PI(s) plan to allocate annually to the proposed project.

Funds can be used for salaries and benefits of the project team, laboratory supplies, subject trial costs, equipment (maximum of 10 percent of the total grant funds) and publication charges for manuscripts that pertain directly to the proposed project. Funds can be requested for regular communications if a co-PI is located at a different institution.

Identify by name and title all project personnel. If a team member is a postdoctoral or clinical fellow, graduate student and/or research assistant. For positions that are not yet filled, indicate "TBD" in the name field.

For institutions that mandate payment of indirect costs, a maximum of 10 percent of the grant may be used for this purpose across all institutions. 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 or for-profit entity, nor for any research expenses related to the project that are incurred by these individuals.

D. **Project Milestones and Timeline.** Complete on the template available from the proposalCENTRAL application website. (Refer above on page 8, 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 the research aims and the estimated time it will take to complete each. Identify the contact PI, title of proposed project and the specific aims at the top of the template. Under each time period, specify the milestones and deliverables that will be accomplished. For each milestone and deliverable, note the corresponding aim in parentheses. Rows may be added/deleted to the template as needed. Should you receive the grant, this template will be used as part of your progress reports.

E. **Biographical Sketch of Contact PI.** The biographical sketch must be in English. The NIH Biographical Sketch Form (PHS 398/2590 [Rev. 06/09]) and (OMB No. 0925-0001/0002 [Rev. 08/12]) are both acceptable. The contact PI must adhere to the page limits and requirements specific to the biographical sketch format used (four pages for the Rev. 06/09 format, five pages for the Rev. 08/12 format).

F. **Biographical Sketch of Co-PI.** Required if a co-PI is included on the proposed project. The biographical sketch must be in English. The NIH Biographical Sketch Form (PHS 398/2590 [Rev. 06/09]) and (OMB No. 0925-0001/0002 [Rev. 08/12]) are both acceptable. The co-PI must adhere to the page limits and requirements specific to the biographical sketch format used (four pages for the Rev. 06/09 format, five pages for the Rev. 08/12 format).

G.   Letter of Commitment from Co-PI. Required if a co-PI is included on the proposed project. The letter should confirm the scope of the co-PI's involvement in the proposed project, including the percent effort, and be addressed to the Scientific Review Committee

H.   Letter(s) of Institutional Support. Letter(s) are required for the contact PI and, if included on the proposed project, for the co-PI. The letter must be written on letterhead by the department head, dean or other senior member of the institution and should be addressed to the Scientific Review Committee. It should explain the relationship of the PI(s) with the institution, the nature and extent of support for the proposed research that is available from the institution, including laboratory space, financial support and other resources and confirm that the proposed project will not present a conflict of interest with the PI's other responsibilities and commitments.

I.   Letter(s) of Commitment from Collaborator(s). A Letter of Commitment is required from all collaborators, including drug or agent suppliers, other organizations providing materials or data and collaborating investigators. The letter should clearly state the specific commitment of the collaborator, whether the involvement is contingent on any factors and the timing of the involvement. The letter should be written on letterhead by the signing institution or company and should be addressed to the Scientific Review Committee.

J.   Appendix (if needed). Upload all approved organizational assurances in the Appendix. Otherwise, appendices should only be used for unpublished manuscripts, clinical trial protocols and large size versions of figures and/or detailed legends presented in the Proposed Project narrative (see page 11, Section V).

   NOTE: This section should not be used to increase the Proposed Project page limit. Use of the Appendix is restricted to no more than two pages for figures and/or legends. Overuse or misuse of this section may result in an application being rejected or the Appendix being removed from the application.

K.   Signed Acknowledgment of Grant Agreement Terms and Conditions. To ensure that the appropriate parties are informed of the terms and conditions of the grant, a copy of the Grant Agreement Terms and Conditions must be downloaded from the proposalCENTRAL application Web page. The final page of the document must be signed by the contact PI and sponsoring institution, indicating that they have read the document. A scanned copy of the signed page must be uploaded into the online application in the section for attaching files.

L.   Application Signature Pages. In order to ensure the appropriate parties have approved the application, the signature pages, as described in Section 12 below, must be printed and signed. The signed signature page (with original signatures from the contact PI and institution's signing official) must then be scanned and uploaded into the online application in the section for attaching files. Signatures that are electronically transmitted shall have the same force and effect as original signatures.

Uploading the attachments into your application. All attachments must be converted to PDF files. To ensure your PDF files upload in their entirety, please avoid replacing files multiple times, using files that were once password-protected or encrypted and combining multiple scanned documents or files into one PDF.

- 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 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 (offline), 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 THE COMPLETE APPLICATION

10. **Contact PI Data Sheet.** This is an automatically populated data sheet based on the contact PI's proposalCENTRAL profile. Information for gender, race and ethnicity must be provided. If fields are not populated, go to Section 4, Contact PI (Applicant), and select the "Edit Professional Profile" tab in the center of the screen. The contact PI 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 Scientific Review 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, 6, 7 and 8 of the online application (these sections also correspond to the sections of the Applications Instructions), you may print the Signature Pages. Click the "Print Signature Pages" button.

    NOTE: Data that you entered in Sections 1, 4, 5, 6, 7 and 8 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 because the information is not required for this grant. If the institution's Employer Identification Number (EIN) is not completed on the Signature Pages, please request your institution to provide that information in their proposalCENTRAL profile.

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

    Please review your entire PDF application to ensure that it contains all the required uploaded materials and the full Scientific Abstract.

Obtain required signatures. The Pancreatic Cancer Action Network requires that the completed application and Signature Pages with original signatures be uploaded into the Application Documents. Signatures transmitted by electronic means shall have the same force and effect as original signatures.

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 email 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.

CHANGING YOUR APPLICATION

Withdrawal of application

Please advise the Pancreatic Cancer Action Network promptly, in writing, should you decide to withdraw your application. Your email (or letter) should include your name, the title of the proposal and the reason for withdrawal.

Change of address

Notify the Pancreatic Cancer Action Network in writing of any changes of address, email 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 the Pancreatic Cancer Action Network to determine whether your application is still eligible for funding consideration.

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 (800) 875-2562 or by email at pcsupport@altum.com.

Inquiries about the Translational Research Grant guidelines and application materials should be directed to the Pancreatic Cancer Action Network at grants@pancan.org or (310) 725-0025. Contact person: Amber Wynn, Associate Director, Research Grants Department.

THE **PANCREATIC CANCER ACTION NETWORK** is the national organization creating hope in a comprehensive way through research, patient support, community outreach and advocacy for a cure. The organization is leading the way to increase survival for people diagnosed with this devastating disease through a bold initiative — The Vision of Progress: Double Pancreatic Cancer Survival by 2020. Together, we can Wage Hope in the fight against pancreatic cancer by intensifying our efforts to heighten awareness, raise funds for comprehensive private research, and advocate for dedicated federal research to advance early diagnostics and better treatments and increase chances of survival.