



2016 PANCREATIC CANCER ACTION NETWORK RESEARCH ACCELERATION NETWORK GRANT AND RESEARCH ACCELERATION NETWORK-2 GRANT

Guidelines and Application Instructions

PANCREATIC
CANCER
ACTION
NETWORK

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CONTENTS

I. GUIDELINES

1 BACKGROUND

1 CLINICAL TRIAL GRANTS

- 1 Option A: Research Acceleration Network (RAN) Grant
- 1 Option B: Research Acceleration Network (RAN)-2 Grant
- 2 Applicant eligibility
- 2 Project eligibility
- 3 Clinical trial endpoints
- 4 Oversight and management
- 4 Use of funds
- 5 Disbursement of funds
- 6 Community for Progress

6 EVALUATION OF APPLICATIONS

II. APPLICATION INSTRUCTIONS

8 APPLICATION PROCEDURES

9 GETTING STARTED IN PROPOSALCENTRAL

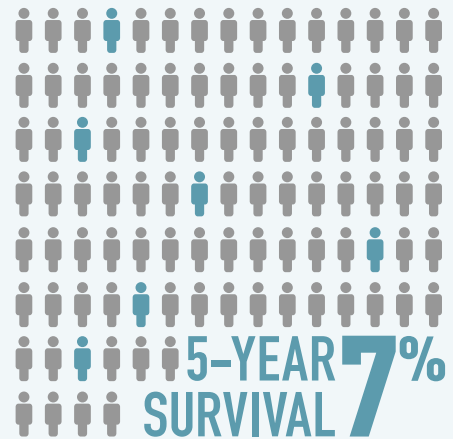
9 COMPLETING THE APPLICATION

16 SUBMITTING THE COMPLETE APPLICATION

16 CHANGING THE APPLICATION

17 INQUIRIES

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



ADVANCE RESEARCH.
SUPPORT PATIENTS.
WAGE 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 this 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 poised 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 2013, the Pancreatic Cancer Action Network launched the Research Acceleration Network (RAN) Grant, which provides \$1 million over one to three years to support research that includes a clinical component designed to improve the detection or treatment of pancreatic cancer. Since then, seven promising multi-institutional projects have been funded by these grants.

In 2016, we will continue to offer RAN Grants and have expanded the eligibility criteria to include projects that deal with detection and treatment as well as prevention and supportive care. Based on our experiences with the RAN Grant and the pressing urgency to further speed improvements, we are pleased to introduce a new clinical research funding mechanism for 2016, the Research Acceleration Network (RAN)-2 Grant, which will support a more advanced project that is expected to have more immediate patient benefits. The RAN-2 Grant provides \$2 million in funding for a Phase II treatment clinical trial or a robust nontherapeutic trial in pancreatic cancer. The grant term can range from one to three years.

CLINICAL TRIAL GRANTS

Option A: Research Acceleration Network (RAN) Grant

provides \$1 million in funding for research in pancreatic cancer that includes a clinical project with an endpoint that improves prevention, detection/diagnosis/prognosis, treatment or supportive care. The grant term can range from one to three years, depending upon the project scope and milestones. The clinical component must be implemented no later than the beginning of the last year of the grant term. The project must involve at least two institutions and demonstrate strong potential to improve outcomes for pancreatic cancer patients. It is anticipated that two RAN Grants will be awarded.

Option B: Research Acceleration Network (RAN)-2 Grant

provides \$2 million in funding over one to three years for research in pancreatic cancer that includes a Phase II treatment clinical trial or a robust prevention, detection/diagnosis/prognosis or supportive care trial implemented no later than the beginning of the second year of the grant term. At least two institutions must be involved in the project, and the impact on pancreatic cancer patients should be immediate, if not as soon as possible. Grant payments are triggered by proof of subject enrollment and trial participation. It is anticipated that one RAN-2 Grant will be awarded.



The deadline for submitting an application for a RAN or RAN-2 Grant is Friday, January 15, 2016, at noon Eastern Standard Time. Funding decisions will be available May 2016. The grant term starts July 1, 2016.

Applicant eligibility

- One applicant, designated the contact principal investigator (contact PI), and at least one co-principal investigator (co-PI) from two distinct institutions are required.
- Additional co-PIs will be considered if their contribution is justified and adds a critical perspective to the project.
- Each PI must be an independent investigator and have a doctoral degree (including PhD, MD, DO, PharmD or equivalent) in the biomedical sciences or in a field applicable to health science research.
- The contact PI must be affiliated with an academic, medical or research institution **within the United States**.
- There are 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.
- Co-PI(s) can be affiliated with any academic, medical or research institution in the world.
- The project team must have the expertise to lead all aspects of the proposed project, including a clinical trial.
- A researcher can be designated a contact PI on one application, either for a RAN or a RAN-2 Grant.
- 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 at least one co-PI who are independent investigators and hold doctoral degrees



At least 2 institutions



Contact PI must be affiliated with a US academic, medical or research institution



Co-PI(s) can be affiliated with any academic, medical, or research institution in the world



Expert team with multidisciplinary experience

Project eligibility

The RAN and RAN-2 Grants are designed to streamline and accelerate progress and effect the desired change in clinical outcome for pancreatic cancer by linking synergistic capabilities, creating an efficient management structure and providing funds that can be rapidly and strategically deployed. The basis for these grants is the recognition that there is high-potential research already underway that provides a strong foundation that can contribute to the 2020 goal of doubling survival for the disease. Funded projects will leverage existing knowledge and experience and be milestone- and timeline-driven. Each project will include metrics of success and measurable goals, and will represent a critical step in a longer-term effort that goes beyond the budget and timeframe of the grant. Plans for subsequent clinical studies and the feasibility of their completion will be presented. Clinical impact, validity, feasibility and, importantly, readiness are overriding evaluation criteria in selecting the projects to fund.

Proposed projects must fall within at least one of the following categories of the Common Scientific Outline: Prevention; Early Detection, Diagnosis and Prognosis; Treatment; and Cancer Control, Survivorship, and Outcomes Research [<https://www.icrpartnership.org/CSO.cfm>].

The following scenarios are considered areas where there are sufficient developments within the pancreatic cancer field that could benefit from strategic acceleration. These are areas that could qualify for funding from either the RAN or RAN-2 Grant, depending upon the stage in which the proposed project falls in the research discovery process. Project stage, scope

and budget needs would determine the best fit for the proposed project. Only those projects that include a clinical trial that realistically will be implemented at the beginning of the first year of a one-year grant or by no later than the beginning of the second year of a multiyear grant (the maximum grant term is three years) will be eligible for consideration for a RAN-2 Grant.

Note that these are examples, and applications are not restricted to projects that conform to these scenarios.

- New approaches to prevention of pancreatic cancer, including preventive drugs.
- Retrospective study for an early detection or predictive serum biomarker panel with a feasible strategic plan for a prospective study. (The prospective study may be outside of the grant term budget and timeframe but will be feasibly completed by the year 2020.)
- A clinical study that integrates assays, markers and/or imaging tests to determine the clinical utility of the biomarker(s) for use in future trials.
- A therapeutic trial that uses an integral biomarker to define eligibility or assign patients to study arms.
- Drug delivery strategies to target the stroma or tumor.
- Neoadjuvant clinical study with tumor tissue for predictive and/or pharmacodynamics marker development.
- Preclinical testing of rational combinations of chemotherapeutic agents currently in early phase clinical development and initial combination clinical trials. (A plan must be included for subsequent clinical testing of resulting promising combinations if this exceeds the timeframe or budget of the RAN or RAN-2 Grant.)
- Clinical bioavailability studies for a promising imaging agent and the initiation of studies in a high-risk cohort.
- Symptom management trials that focus on treatment for fatigue and cachexia.
- An immunotherapy approach that clinically tests combinations of a previously-tested vaccine with one or several immune modifying factors.

Clinical trial endpoints

The clinical trials that are funded by RAN and RAN-2 Grants will be milestone- and timeline-driven. As part of the application, measurable endpoints will need to be identified, annual goals established for each of the selected metrics and a statistical plan included for measuring progress toward stated goals.

The following are metrics that are commonly used as clinical trial endpoints. **Note that these are examples and applicants are not restricted to select from this list.**

- For prevention trials: biomarker-, imaging- and pathology-based endpoints.
- For diagnostic/detection trials: sensitivity, specificity and predictive values of the biomarker or test.
- For treatment trials: median progression free survival (PFS), median overall survival (OS), relative one-year survival, objective response rate (RECIST criteria) and hazard ratios (HR).
- For supportive care trials: ECOG or Karnofsky performance status, functional limitations (FL), body composition (BC) and health-related quality of life (HRQOL) measurements. These can pertain to symptoms caused by the disease itself or from therapy.

Oversight and management

The project funded by a RAN or RAN-2 Grant will be directed by a Steering Committee created by the contact PI and co-PI(s). The purpose of the Steering Committee is to provide input and guidance on the proposed project, help determine course adjustments that may be needed, and approve unanticipated and justified changes in the project budget. The contact PI and co-PI(s) serve on the Steering Committee. All Committee members have equal decision-making authority. Applicants are encouraged to select members for their unique and needed expertise. Broad representation is recommended from academia, industry, clinical practice, government, etc. The development of the Steering Committee is an opportunity for PIs to forge new collaborations and ensure diverse perspectives inform the funded project. A representative from the Pancreatic Cancer Action Network leadership may participate in Steering Committee meetings and will vote only in the case of a stalemate.

A staff member from the Pancreatic Cancer Action Network's Research Grants Department will serve as the overall Project Manager. The intent of this position is to provide strategic project management support and help optimize project implementation and progress. The overall Project Manager will convene regularly scheduled teleconferences with the PIs to discuss progress and next steps, coordinate Steering Committee activities, assist in the transfer of reagents and information, facilitate the completion of compliance and regulatory documents and help resolve unexpected issues. Specific responsibilities may vary across projects and are developed in collaboration with the contact PI and co-PI(s) to ensure that this position best meets the needs of the funded project. The position is supported outside of the grant by the Pancreatic Cancer Action Network.

Funds from the grant may be used to support an onsite project manager to coordinate activities with the overall Project Manager. Project managers will not be voting members of the Steering Committee.

Use of funds

Funds from the RAN and RAN-2 Grants support project expenses over a one to three year period. Maximum funding is \$1 million for a RAN Grant and \$2 million for a RAN-2 Grant. The budget should be estimated for each year of the grant term, but will be regularly reviewed by the Steering Committee to allow for modifications in response to unanticipated and justified needs. There will be no carryover of funds beyond the grant term. Since this is an acceleration grant and the intent is to speed patient outcomes, investigators are urged to consider planning to complete the project in advance of a three-year end date, if realistic.

Funds can be used for salaries and benefits for the project team, including onsite project management personnel, laboratory supplies, equipment (maximum of 10 percent of total grant), quality assurance and regulatory compliance, subject clinical trial costs and publication charges for manuscripts that pertain directly to the funded project. Expenses must be budgeted for regular communications and information exchange between the contact PI and co-PI(s) and for travel for face-to-face Steering Committee meetings. For institutions that mandate payment of indirect costs, a maximum of 10 percent of the total grant may be used for this purpose.



Tuition, professional membership dues, general office supplies, individual institutional administrative charges (e.g., telephone, other electronic communication, IT network, etc.), pre-award charges and any other expenses not directly related to the project are not allowable expenses. In addition, no grant funds may be directed to employees or subcontractors of a government or for-profit entity.

Disbursement of funds

Grant payments are made directly to the contact PI's institution and that institution is responsible for entering into subcontracts and managing subcontracts involved with the proposed project.

For a **RAN GRANT**, the Pancreatic Cancer Action Network will disburse funds to the contact PI's institution according to the approved project budget.

- The number of installments will depend on the length of the grant term and will range from three payments for a one-year grant to up to seven payments for a three-year grant.
- The last payment will consist of a 5 percent holdback until final grant reports are approved by the Pancreatic Cancer Action Network.

For a **RAN-2 GRANT**, disbursements to the contact PI's institution will be as frequent as quarterly each year and are linked to milestones being achieved for subject accrual and trial participation. More specifically:

- Indirect expenses (maximum of 10 percent of the total grant) will be disbursed on a prorated basis across all grant payments.
- The last payment will consist of a 5 percent holdback until final grant reports are approved by the Pancreatic Cancer Action Network.
- The remaining funds will be divided by the total number of subjects that are expected to be accrued during the grant term to determine the "per subject payment." Each grant disbursement will include payment for each subject that was actually accrued and started the trial during the reporting period.
- For multiyear grants, up to 10 percent of the grant funds can be available in the first year for research and administrative activities to meet compliance and regulatory requirements, in order to ramp up for trial commencement. If these expenses are justified, then they will be removed from the total funds, along with indirect expenses and the holdback for the final grant reports, before calculating the "per subject payment."

Comparisons between RAN and RAN-2 Grants

	RAN GRANT	RAN-2 GRANT
<i>Maximum funding</i>	\$1,000,000	\$2,000,000
<i>Grant term</i>	1-3 years	1-3 years
<i>Clinical trial start date</i>	No later than the beginning of the last year of the grant	Phase II treatment trial or robust nontherapeutic trial starts no later than the beginning of year 2 of the grant
<i>Grant disbursements</i>	According to approved budget.	Linked to subject accrual and trial participation. If Phase II or robust trial not planned until year 2, maximum of 10% of grant funds available in year 1 for research and administrative activities related to compliance and regulatory requirements.
<i>Carryover beyond year 3</i>	No	No
<i>Institutional indirect costs allowed</i>	10% of grant funds	10% of grant funds
<i>Holdback until final reports approved</i>	5% of grant funds	5% of grant funds
<i>Project management provided by Pancreatic Cancer Action Network</i>	Yes	Yes

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 18-21, 2016, in San Diego, CA. Applicants for a RAN or RAN-2 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

The RAN and RAN-2 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/or 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 the proposed project a match for the grant and is there sufficient evidence that the clinical component will be launched by the required time (no later than the beginning of the last year of the term for a RAN Grant and by the beginning of year 2 for a RAN-2 Grant)?
- Do the plans for clinical experimentation represent the appropriate next steps?
- Are the project aims and activities realistic and timely?

Clinical impact

- Does the clinical research address a legitimate and pressing medical or scientific question relevant to pancreatic cancer?
- Are appropriate metrics identified for measuring clinical impact and patient benefit? Are annual performance targets specified and is there a reasonable plan for assessing their achievement?
- If successful, will the proposed project inform and have a demonstrated impact on improving clinical practice?

Scientific validity

- Is there a strong scientific rationale to the proposed project?
- Have the appropriate foundational studies been performed to demonstrate and support the scientific validity of the proposed concept?

Feasibility

- Is the overall project feasible?
- Is the clinical protocol reasonable and likely to result in the maximum amount of data?
- Is the recruitment strategy well thought out and is there evidence to expect stable subject accrual for the clinical research?
- Is the project designed to meet ethical guidelines concerning human subjects in research?
- Are all the needed resources, including drugs and agents, readily available?
- Are proposed expenses justifiable and reasonable in relation to the proposed project?
- Have possible barriers to progress been anticipated, and are solutions and alternative strategies proposed?

Project team

- Do the PIs have the appropriate training, expertise and track record of accomplishments and leadership 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?
- Is the Steering Committee appropriately constituted?
- Are the communication plans 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?
- Does the proposed project have strong potential to contribute to the goal of doubling pancreatic cancer survival by 2020?

II. APPLICATION INSTRUCTIONS

APPLICATION PROCEDURES

Applications must be submitted by **noon Eastern Standard Time on Friday, January 15, 2016**, using the proposalCENTRAL website at <https://proposalcentral.altum.com>.

To submit a complete application, applicants need 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	<i>Instructions/ proposalCENTRAL Section</i>
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
Secured Support Template	9.B
Other Pending Support Template	9.C
Budget and Budget Narrative Template	9.D
Project Milestones and Timeline Template	9.E
Steering Committee Roster Template	9.F
Steering Committee Member Confirmation Template	9.G
Non-template materials to be uploaded	
Biographical Sketch of Contact PI	9.H
Biographical Sketch of Co-PI(s)	9.I
Letter(s) of Commitment from Co-PI(s)	9.J
Letters of Institutional Support	9.K
Letter(s) of Commitment from Collaborator(s) (including those supplying resources)	9.L
Appendix (if needed)	9.M
Materials to be downloaded, printed, signed, scanned and uploaded	
Signed Acknowledgment of Grant Terms and Conditions	9.N/12
Application Signature Pages	9.O

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 “Research Acceleration Network Grant/Research Acceleration Network-2 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 (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 Templates and Instructions.** The Guidelines and Application Instructions document, the Grant Terms and Conditions and all templates can be downloaded from this page.

An Application Packet Checklist also is 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 templates must be downloaded and completed: Research Project Proposal Template, Secured Support Template, Other Pending Support Template, Budget and Budget Narrative Template, Project Milestones and Timeline Template, Steering Committee Roster Template and Steering Committee Member Confirmation 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 Project Milestones and Timeline Template 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.

See below on page 15 in the Application Instructions for how to complete and upload the templates.

The following additional attachments, for which a template is not provided, are also required: Biographical Sketch of Contact PI; Biographical Sketch of Co-PI(s); Letter(s) of Commitment from Co-PI(s); Letters of Institutional Support; Letter(s) of Commitment from Collaborator(s) (including those supplying resources); and Appendix (if needed).

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

4. Contact-PI (Applicant) Information. Enter information for the contact PI directly into the proposalCENTRAL system. Contact PIs are required to update their Professional Profile, including their contact information, other support and publications.

5. Institution and Contacts. Enter information regarding the contact PI's institution and the designated signing official directly into the proposalCENTRAL system.

6. Project Team. Enter contact information for the co-PI(s), investigators and other key personnel that will compose the project team directly into proposalCENTRAL. 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. Include the project justification, description of the background research, overview of the proposed project including the clinical design, subject recruitment strategy and accrual targets, endpoint metrics, plans for measuring outcomes and how the proposed project will contribute to the goal of doubling survival for pancreatic cancer by 2020.

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 describe 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, figures or other images.
- **Spacing.** Single-spaced format, and indent to begin new paragraphs.
- **Page margins.** No less than 0.75 inches 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 9, Section 2, in the Application Instructions for details.) The information must be presented in this order:

I. Table of Contents Page. Complete the Table of Contents by indicating the appropriate page number for each section.

II. Application Classification. Complete Sections A-F as follows:

- | | |
|---|---|
| A. Title of Proposed Project
(maximum 75 characters, including spaces) | E. Phase of Clinical Trial that would be
Implemented by this Grant
(Phase 0, Phase Ia, Phase Ib, Phase II,
Nontherapeutic Trial) |
| B. Type of Grant Application
(RAN Grant or RAN-2 Grant) | F. Year of Grant in Which Clinical Trial Would
Begin (Year 1, Beginning of Year 2 or
Beginning of Year 3) |
| C. Requested Length of Grant
(1 Year, 2 Years or 3 Years) | |
| D. Type of Clinical Trial Proposed for Funding by
this Grant (Prevention, Detection/Diagnosis/
Prognosis, Treatment or Supportive Care) | |

III. Lay Abstract. This abstract, limited to 3,000 characters (including spaces), should be different from the scientific abstract described on page 10, Section 7 in the Application Instructions. Please use language suitable for a **non-scientific audience** and provide a clear, concise and comprehensive overview of the proposed project. Do not use abbreviations. Summarize the justification and background research for the proposed project; how the proposed project builds on existing work, including initial clinical research that has occurred and the results of this research; the purpose, aims and study design of the proposed project; how results will benefit patients and improve clinical practice; and plans for measuring and evaluating progress.

IV. Proposed Project. Maximum 15 pages, including tables, figures and other images. The information presented in this section describes the justification and background research that has been completed, details of the proposed project, compliance and regulatory requirements that need to be completed before the clinical trial commences and plans for next steps that go beyond the timeframe and budget of the requested grant. The information must be presented in the order specified and include these subheadings:

- | | |
|---|--|
| A. Justification and Background Research | C. Clinical Trial (include subsections 1-13) |
| B. Pre-Trial Research (include subsections 1-4) | D. Next Steps |

V. Multi-Institutional Team. Maximum 2 pages. Describe the benefits and value-added activities this multi-institutional team brings to the proposed project. Discuss the plan for coordinating the proposed project across multiple institutions. Information should be presented in the order specified and include these subheadings:

- A. Team Benefits B. Coordination Plan

VI. Communication Plans. Maximum 2 pages. Describe plans for maintaining regular communications and information exchange among the contact PI and co-PI(s). Discuss the plan for communicating with the Steering Committee so that members are kept informed of the project progress and are equipped to effectively participate in decision-making, as needed. Information should be presented in the order specified and include these subheadings:

- A. Communication Plan for PIs B. Communication Plan for Steering Committee

VII. Facilities. Maximum 2 pages per institution. Please describe the research facilities, resources and equipment that are available to the contact PI and co-PI(s) that will allow successful implementation of the proposed project. Include descriptions of each of their institutions. Also describe any other institutions that will be involved in the proposed project that are expected to receive grant funds, and the resources they will contribute.

VIII. References. Include publications on the foundational research and, as appropriate, clinical research that were authored by the contact PI and co-PI(s). 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. Secured Support. Complete on the template available from the proposalCENTRAL application website. (Refer above on page 9, Section 2, in the Application Instructions for details.) Provide details of all existing support (institutional, federal, etc.) that has been secured and will be used in whole or in part by the contact PI and/or co-PI(s) during the term of this grant (maximum duration 7/1/16 - 6/30/19). List all support for the contact PI and co-PI(s), including funding for which they are 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/Co-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 RAN or RAN-2 Grant would expand on this funding, but not constitute an overlap. Information should be presented in the order specified and include these subheadings:

- | | |
|--|---|
| A. Secured Support for Contact PI | C. Secured Support for Co-PI |
| B. Other Support for Proposed Project for Contact PI | D. Other Support for Proposed Project for Co-PI |

If there is more than one co-PI, add tables to the template for each additional co-PI to list their Secured Support. If they have secured funding for one or more aims included in the proposed project, explain how the RAN or RAN-2 Grant would expand on this funding but not constitute an overlap.

C. Other Pending Support. Complete on the template available from the proposalCENTRAL website. (Refer above on page 9, Section 2, in the Application Instructions for details.) Provide details of all pending support (institutional, federal, etc.) that will, if secured, be used in whole or in part by the contact PI and/or co-PI(s) during the term of this grant (maximum duration 7/1/16 - 6/30/19). List all pending support for the contact PI and co-PI(s), including funding for which they are not the principal investigator. This may include support for different projects. For each pending 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/Co-PI, and List of Specific Aims as Stated in Grant Proposal (summaries will not be accepted).

If there is more than one co-PI, add tables to the template for each additional co-PI to list their Other Pending Support.

- D. Budget and Budget Narrative.** Complete on the template available from the proposalCENTRAL website. (Refer above on page 9, Section 2, in the Application Instructions for details.) The RAN and RAN-2 Grants provide support for one to three years. Maximum funding is \$1 million for a RAN Grant and \$2 million for a RAN-2 Grant. The budget should be estimated for each year of the grant term. In addition to contact PI and co-PI(s) institutions, any other institution involved in the proposed project that expects to receive grant funds should be included.

Funds can be used for salaries and benefits for the project team, including on-site project management personnel, consultants, laboratory supplies, equipment (maximum of 10 percent of total grant across all institutions), quality assurance and regulatory compliance, subject clinical trial costs and publication charges for manuscripts that pertain directly to the funded project. Expenses must be budgeted for regular communications and information exchange among the contact PI and co-PI(s) and the project team, and for travel for face-to-face Steering Committee meetings. If applying for a RAN-2 Grant, if the Phase II treatment clinical trial or robust nontherapeutic trial is not planned to start until the beginning of the second year, a maximum of 10 percent of the requested grant can be budgeted in the first year for research and administrative activities relating to compliance and regulatory requirements.

Identify by name and title all project personnel. Note 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.

Contact PI and co-PI(s) must indicate the percentage of time they each will spend on the proposed project and their salary. If any part of their salary is requested to be funded by the RAN or RAN-2 Grant, the percentage of salary requested may not exceed the percent effort they will dedicate to the project.

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 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, nor for any research expenses related to the project that are incurred by these individuals.

- E. Project Milestones and Timeline.** Complete on the template available from the proposalCENTRAL website. (Refer above on page 9, 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. If your proposed grant term is less than three years, only use the portion of the template that corresponds to the proposed duration of your requested RAN or RAN-2 Grant. Should you receive the grant, this template will be used as part of your progress reports.

- F. Steering Committee Roster.** Complete on the template available from the proposalCENTRAL website. (Refer above on page 9, Section 2, in the Application Instructions for details.) The Steering Committee Roster includes names, titles, affiliations and expected contributions each member will make to the proposed project. Applicants are encouraged to create a committee that includes a broad base of expertise from industry, academia, clinical practice, government, etc. The contact PI and co-PI(s) should be listed as members of the Steering Committee.
- G. Steering Committee Member Confirmation.** Complete on the template available from the proposalCENTRAL website. (Refer above on page 9, Section 2, in the Application Instructions for details.) A Confirmation form must be completed and signed by each member of the Steering Committee (except for the contact PI and co-PI(s)). Electronic signatures are acceptable.
- H. 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. Please 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).
- I. Biographical Sketch of Co-PI(s).** 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 applicant 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).
- J. Letter(s) of Commitment from Co-PI(s).** A Letter of Commitment must be uploaded for each co-PI. The letter should confirm the scope of the co-PI's involvement in the proposed research.
- K. Letters of Institutional Support.** A Letter of Institutional Support must be uploaded for the contact PI and each 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 contact PI's or co-PI's relationship with the institution; the nature and extent of support for the proposed project 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.
- L. 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 must be written on letterhead by the signing institution or company and should be addressed to the Scientific Review Committee.
- M. Appendix (if needed).** Appendices should only be used for clinical trial protocols, unpublished manuscripts and large size versions of figures and/or detailed legends presented above in the Proposed Project narrative (see page 11, Section A. IV.)

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.

N. Signed Acknowledgment of Grant Terms and Conditions. To ensure that the appropriate parties are informed of the terms and conditions of the grant, a copy of the Grant 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.

O. Application Signature Pages. In order to ensure that 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. Once converted, the next step is to upload the files into 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 dropdown 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 or 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 Application 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 these grants. 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, Project Team 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 required 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 validation 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 THE APPLICATION

Withdrawal of application

Please advise the Pancreatic Cancer Action Network promptly, in writing, should you decide to withdraw your application for any reason. Your email (or letter) should include your name, the type of award you applied for, 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 RAN and RAN-2 Grant guidelines and application materials should be directed to the Pancreatic Cancer Action Network at grants@pancan.org or (310) 725-0025. Contact person: Rhonda Aizenberg, PhD, 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.