



2017 PANCREATIC CANCER ACTION NETWORK
**EARLY DETECTION
TARGETED GRANT**

Guidelines and Application Instructions

PANCREATIC
CANCER
ACTION
NETWORK®

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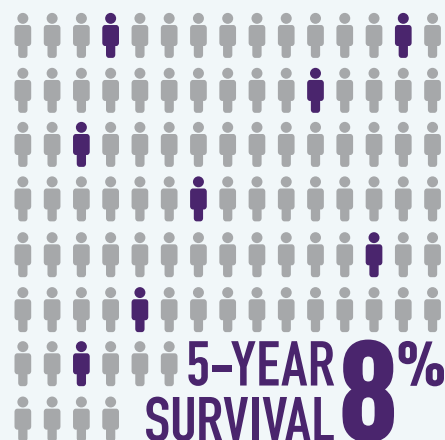
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PANCREATIC CANCER
HAS THE LOWEST
FIVE-YEAR RELATIVE
SURVIVAL RATE
OF ALL MAJOR CANCERS



ADVANCE RESEARCH.
SUPPORT PATIENTS.
CREATE HOPE.

Please direct questions to:

Lynn M. Matrisian, PhD, MBA, Chief Research Officer
Pancreatic Cancer Action Network
lmatisian@pancan.org or (202) 772-3373



I. GUIDELINES

SUMMARY

This Request for Applications is to support ancillary research studies that identify promising blood biomarkers or imaging approaches that will eventually facilitate the use of specimens and/or participants in a cohort of new-onset diabetics and validate components of a protocol for the early detection of pancreatic ductal adenocarcinoma. Applicants may propose up to four Units, (or projects) with a specific goal and clearly defined, quantifiable outcome measures. Each Unit must indicate a separate budget, not to exceed \$250,000, for a period of up to two years. The total amount requested may not exceed \$1 million total for a total time period of four years.

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 believes the current approach to pancreatic cancer needs to be rewritten with a focus on what is best for an individual patient. Initiatives such as Patient Central, Clinical Trial Finder, Patient Registry, Know Your TumorSM and Precision Promise are designed to empower the patient and facilitate access to information that provides the best opportunity for the individual as well as contributes to advancing the field for future pancreatic cancer patients.

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 DETECTION OF PANCREATIC CANCER INITIATIVE

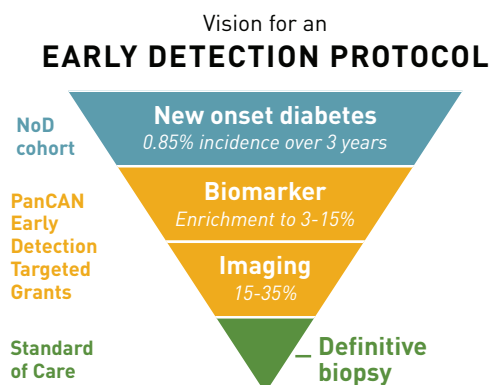
Pancreatic ductal adenocarcinoma (PDAC) is the deadliest of the major cancer types, with a five-year survival rate in the single digits. Surgical resection offers the only hope of prolonged survival, but fewer than 20 percent of patients are eligible for resection as the disease is frequently diagnosed at an advanced stage. Dramatic improvements in the five-year survival rate for pancreatic cancer will require advances in early detection to improve resectability rates and the development of chemotherapeutic agents to prolong survival following resection. The Pancreatic Cancer Action Network has announced Precision Promise to accelerate the development of targeted chemotherapeutic agents for advanced PDAC. In parallel, we are partnering with the National Institutes of Health to support ancillary research to develop a validated screening protocol

for the early detection of PDAC in a cohort of adults with new-onset diabetes (NoD). One in 125 individuals with sudden, adult onset diabetes are diabetic as a consequence of undiagnosed pancreatic cancer, making this the only feasible screenable population of individuals with sporadic PDAC. The ultimate goal of the Early Detection Initiative is a viable screening protocol that is sufficiently sensitive, specific and cost-effective in identifying PDAC at a stage that enables surgical intervention to improve outcomes.

The National Institute for Diabetes and Digestive and Kidney Diseases and the National Cancer Institute initiated the [Chronic Pancreatitis, Diabetes, and Pancreatic Cancer Consortium \(CPDPC\)](#) in late 2015. Starting in spring 2017 and over the next three years, the CPDPC plans to assemble a cohort of 10,000 subjects over age 50 years with new-onset diabetes, called the NoD cohort. The purpose of the NoD cohort includes establishing a biobank of clinically annotated biospecimens, including a reference set of biospecimens from pre-symptomatic PDAC and control new-onset type 2 diabetes mellitus subjects, and facilitating the validation of emerging tests for identifying NoD subjects at high risk for having PDAC using this reference set. It is expected that 85 incidences of PDAC will be diagnosed during the study.

The Pancreatic Cancer Action Network, in collaboration with the investigators of CPDPC, plans to support ancillary research studies that identify promising blood biomarkers or imaging approaches that can utilize the NoD cohort specimens and/or participants to retrospectively validate an approach to the early detection of PDAC. The NoD specimens should be available for analyses two years after the commencement of NoD cohort accrual.

The expectation is that 0.85 percent of individuals in the NoD cohort will be diagnosed with PDAC within three years. However, in order for a screening protocol utilizing EUS-guided biopsy to be considered cost effective, the population being evaluated would need an approximate incidence rate of 35 percent. The assumptions are that clinical phenotype information and successful blood-based biomarkers should enrich the population from 0.85 percent having PDAC to 3 to 15 percent. Next, a promising imaging modality should further enrich the population to an incidence rate of 15 to 35 percent PDAC, which makes EUS-guided biopsy feasible and cost effective to lead to a definitive diagnosis (see diagram).



This RFA focuses on identifying blood-based biomarkers to enrich the population from 0.85 percent to around 15 percent pancreatic cancer incidence, or imaging approaches that could further enrich to around 35 percent. Depending on the performance and cost of the combination of the biomarker and imaging strategies, the biomarker performance minimum would be considered 85 percent specificity at 95 percent sensitivity, or 90 percent specificity at 60 percent sensitivity. If successfully validated in a timely manner, opportunities for prospective validation within the NoD cohort will be explored with additional funding from the Pancreatic Cancer Action Network.

About the NoD cohort: Beginning in the spring 2017, 10,000 individuals living in the United States, age 50 to 85 years, diagnosed with diabetes fewer than 90 days prior to enrollment, are expected to be recruited. Part 1 of the NoD cohort trial design is observational and will involve serial blood collection and follow-up for pancreatic cancer diagnosis for three years from enrollment. Part 2 is interventional and will use clinical and biomarker information to identify a subset of participants who will undergo imaging-based diagnostic screening by clinical MRI and/or EUS. Part 2 details are still in development by the consortium.

In the event that there are substantial delays in the development of part 1 of the NoD cohort, steps will be taken by the Pancreatic Cancer Action Network to meet the goals set out by the CPDPC within the anticipated timeframe, and extenuating circumstances will be considered in the implementation of the study plan outlined in funded Early Detection Targeted Grants.

For part 1 of the NoD cohort, samples will be collected at baseline, six, 12 and 24 months after registration, with an additional optional 18-month sample. Subjects will complete a Risk Factor Survey at baseline and a self-administered survey at each follow-up. At each collection time, whole blood will be collected to measure fasting blood glucose and HbA1c, and plasma, serum and buffy coat samples will be processed and frozen at -80°C. Samples and collection methods are according to the NCI's Early Detection Research Network Standard Operating Procedures (details available upon request).

APPLICANT ELIGIBILITY

Applications from academic institutions or for-profit biotechnology or pharmaceutical firms are accepted. There are expectations for reasonable cost- and profit-sharing in contracts with for-profit agencies. The principal investigator must have a doctoral degree (including PhD, MD, DO, PharmD or equivalent) in the biomedical sciences or in a field applicable to health science research. There are no restrictions on citizenship or country of origin, but note that the NoD cohort is currently designed to operate only in the United States.

PROJECT ELIGIBILITY

Projects should be concise steps in the developmental pathway for a biospecimen-based or an imaging approach consistent with the vision for an early detection protocol described above. Projects should be outlined as one or more “Units” with a specific goal and clearly defined, quantifiable outcome measures that will be used to determine if the goal is obtained, if the project should progress to the next Unit and/or to determine suitability of being incorporated into the NoD cohort upon completion of the project. A Unit that incorporates retrospective analysis of the NoD cohort blood samples can be proposed upon completion of a preliminary/validation Unit.

As stated above, two risk assessment modalities can be proposed:

- 1. Biospecimen-based assays:** involves biomarkers (e.g., DNA, RNA, protein, lipids, carbohydrates) for the early detection of pancreatic cancer from any of a variety of biospecimens (e.g., blood, other body fluids or tissues)
- 2. Image-based techniques:** involves imaging approaches (e.g., nanotechnology, fluorescence, MRI or PET) to analyze tissue noninvasively for the early detection of pancreatic cancer and pre-cancer

Below is the foundational data needed to justify proposed projects, as well as examples of projects that can be proposed for each modality:

Biomarkers from biological samples

Foundational data:

Applicants should have followed a developmental pathway for a biospecimen assessment modality (see *Srivastava et al, Clin Can Res 14, 5674, 2008* for example) and will provide evidence of having achieved the following milestones:

- Developed a reproducible assay and standards
 - Evaluated on measures of precision and reproducibility
 - Evaluated on feasibility of widespread dissemination and cost
- Demonstrated reasonable sensitivity and specificity in distinguishing patients with pancreatic cancer from those with no cancer
 - Evaluated on sensitivity of the assay in identifying patients with increasingly earlier stages of pancreatic cancer
 - Evaluated on specificity of the assay in distinguishing pancreatic cancer from confounding conditions

Examples of proposed projects:

The goals of a Unit within this study could be one or more of the following:

- Validation of the assay to identify patients with premalignant or early-stage pancreatic cancer. In this case, the use of samples from pre-symptomatic individuals from cohorts such as the following examples will be considered appropriate (details on relevant samples and contact information available upon request):
 - EDNRN – Early Detection Research Network, Pancreatic Cancer Reference Set
 - PLCO – Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial
 - WHI – Women’s Health Initiative
 - EPIC – European Prospective Investigation into Cancer and Nutrition study

- SCC – Southern Community Cohort
- UKCTOCS – United Kingdom Collaborative Trial of Ovarian Cancer Screening
- Development or refinement of the protocol or reagents to be clinical grade and usable with the NoD cohort samples
- Case/control studies using samples from patients with pancreatic cancer who developed diabetes fewer than three years prior to the diagnosis of cancer
- A request for funds to support the collection of additional samples from NoD cohort participants in the event that samples or sample processing procedures other than those defined by the NoD cohort are required
- Analysis of NoD cohort retrospective samples if previous milestones are met

Imaging approaches to the early detection of pancreatic cancer

Foundational data:

Applicants should have followed a developmental pathway for an image-based assessment modality (for example see *Dorfman et al, Clin Can Res 14, 5678, 2008*) and will provide evidence for having achieved the following milestone:

- The acquisition and analytical parameters of the assay have been optimized in a preclinical or clinical setting
 - Evaluated on the sensitivity of the assay in identifying increasingly earlier stages of pancreatic cancer
 - Evaluated on the specificity of the assay in distinguishing pancreatic cancer from confounding conditions
 - Evaluated on risk and cost-benefit ratio
 - Evaluated on feasibility of widespread dissemination

Examples of proposed projects:

The goals of a Unit within this study could be one or more of the following:

- Optimization of the assay at a single or small number of institution(s) to identify patients with premalignant or very early-stage pancreatic cancer
- Establishing GMP manufacturing procedures for a contrast agent or enhancer for use with the NoD cohort
- Testing the approach on NoD cohort-enrolled participants at a single or small number of institution(s)

USE OF FUNDS

Applications for projects with one to four Units will be accepted. The budget for each Unit is flexible but is capped at \$250,000 total (up to 20 percent, or \$50,000, of the total budget can cover indirect costs) for a time not to exceed two years. The total request shall not exceed \$1 million (up to 20 percent, or \$200,000, of the total budget can cover indirect costs) for a time period up to four years.

Funds can be used for salaries and benefits, laboratory supplies, equipment (maximum of 10 percent of total grant), subject trial costs, travel to present results at national meetings 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 20 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.

When invited, grantees are expected to attend face-to-face meetings specifically related to the integration of ancillary studies into the NoD cohort. Under appropriate circumstances, travel to attend these meetings will be provided separately from the grant by the Pancreatic Cancer Action Network.

EVALUATION OF APPLICANTS

Early Detection Targeted 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 studies. A pancreatic cancer research advocate will also serve on the committee to represent the collective patient perspective. The same or a similarly constituted Committee will be responsible for determining if milestones are achieved and if the project can progress to any additional Units.

The overarching review criteria will be the potential to extend the five-year survival rate and readiness at the end of the project period for incorporation into the NoD cohort study. The assessment of each Unit will be made based on consideration of the following criteria:

Readiness

- Is there a strong scientific rationale and theoretical basis for the proposed approach as a component of the pancreatic cancer screening protocol for individuals with new-onset diabetes?
- Have the appropriate foundational studies been performed to demonstrate and support the relevance, scientific validation and methodological feasibility of the proposed project?
- Do the assay parameters of reproducibility, precision, sensitivity and specificity merit further investment?
- If successful, will the proposed research be ready for incorporation into the NoD cohort within the specified timeframe?

Potential

- Does the proposed project address a high clinical need area that challenges and seeks to shift current clinical practice paradigms to dramatically improve outcomes and accelerate progress against pancreatic cancer?
- 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 samples and reagents, readily available?
- Are proposed expenses fully justified and reasonable in relation to the transformational potential of the proposed project?
- Can the project be scaled and adapted to be feasible and cost-effective within the U.S. healthcare system?

Outcomes

- Is there a plan to measure project outcomes and is it reasonable and appropriate?
- Are quantifiable milestones and deliverables clearly specified and appropriate for determination of suitability for Unit completion and project incorporation into the NoD cohort?

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?



II. APPLICATION INSTRUCTIONS

IMPORTANT DATES

E-application deadline: Applications must be submitted by February 22, 2017, at noon, Eastern Standard Time, using the proposalCENTRAL website at <https://proposalcentral.altum.com>.

Decision Date: Funding decisions will be made in May 2017.

Start date: July 1, 2017

Term: Not to exceed two years for an application consisting of a single Unit or four years for an application requesting more than one Unit.

APPLICATION PROCEDURES

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 an overview of information that needs to be entered and the materials that need to be uploaded.

Information to be entered directly into proposalCENTRAL:

- Title Page
- Contact PI (Applicant) Information
- Institution and Contacts
- Project Team
- Organizational Assurances

Templates to be downloaded, completed and uploaded:

- Research Proposal Template
- Other Financial Support Template
- Budget Template
- Milestones and Timeline Template

Non-template materials to be uploaded:

- Biographical Sketch of Contact PI and All Key Investigators
- Letters of institutional support and letters of commitment for collaborations and reagent provision, etc., as needed

Materials to be downloaded, printed, signed, scanned and uploaded:

- Signed Acknowledgement of Contract Terms and Conditions
- Application Signature pages

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 “Early Detection Targeted 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

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 Contract Terms and Conditions and all templates must be downloaded from this page.
3. 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.
4. 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.
5. Project Team. Enter contact information for investigators and other key personnel that will compose the project team. Project members should be listed separately for each participating institution beginning with the most senior role.
6. 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.
7. Application Templates. Please download the Research Proposal Template, Other Financial Support Template, Budget Template, and Milestones and Timeline Template from proposalCENTRAL and complete according to the directions within each template. Use MS Word or MS Excel to complete the templates. You do not need to be connected to the internet or proposalCENTRAL while working on the templates. Please convert to PDF format before uploading the completed template files to your online application.

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.
8. Upload the other required documents for which templates are not provided.

Biographical Sketch of Contact PI and All Key Investigators

The biographical sketch must be in English. Please use NIH Biographical Sketch Form OMB No. 0925-0001/0002 (Rev. 11/16). The biographical sketch may not exceed five pages.

Letters of institutional support and letters of commitment for collaborations and reagent provision, etc., as needed.

Letters from key personnel should confirm the scope of their involvement on the proposed project. Letters of institutional support should 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. Letters of commitment from collaborators 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.

9. Signed Acknowledgement of Contract Terms and Conditions. The Contract Terms and Conditions must be downloaded and the last page signed by the contact PI and signing official from the sponsoring institution. Please scan and upload the signed document.
10. Application Signature Pages. In order to ensure the appropriate parties have approved the application, the signature pages must be printed and signed. The signed signature page (with original signatures) 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.

SUBMITTING THE APPLICATION

1. 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.

Once converted, the next step is to upload the files to your online application.

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

“DEL” allows you to delete the file, if necessary, and “SHOW” opens the uploaded file. **Open and review your uploaded files.**

In the section for attachments, all the required attachments are listed in the middle of the screen, just below where you upload your files. This list 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.**

2. 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.
3. Signature Pages and Print Application. After completing these sections of the online application, you may print the Signature Pages. Click the “Print Signature Pages” button.

NOTE: Data that you entered in previous sections of the online application are automatically included in the Signature Pages. If information is missing in the Signature Pages, it could be because you have not entered the information in one of the proposal sections OR 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. Please review the application in its entirety by selecting the “Print Signatures Pages and Attached PDF Files” option to ensure that it contains all the required uploaded materials.

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.

4. 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.

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 Early Detection Targeted Grant guidelines and application materials should be directed to the Pancreatic Cancer Action Network at lmatisian@pancan.org or (202) 772-3373. Contact person: Lynn M. Matrisian, PhD, MBA, Chief Research Officer.



THE PANCREATIC CANCER ACTION NETWORK

is the global leader accelerating the pace of research progress for one of the world's deadliest cancers. With an urgent mission to improve outcomes for pancreatic cancer patients and double survival by 2020, the organization, founded in 1999, executes a bold and comprehensive strategy to Wage Hope through research, patient services, advocacy and community engagement. The organization's visionary goals, world-class programs and services, extensive grassroots network, patient-focused outcomes and advisory board of scientific and medical leaders, provide the critical backdrop to help pancreatic cancer patients today and create transformational change for all patients in the future.