I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Pancreatic Cancer Research Program

Translational Research Partnership Award

Announcement Type: Initial

Funding Opportunity Number: HT942524PCARPTRPA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), June 28, 2024
- Invitation to Submit an Application: August 2024
- Application Submission Deadline: 11:59 p.m. ET, October 3, 2024
- End of Application Verification Period: 5:00 p.m. ET, October 8, 2024
- Peer Review: December 2024
- **Programmatic Review:** February 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Pancreatic Cancer Research Program (PCARP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the PCARP in 2020 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the PCARP from FY20 through FY23 totaled \$51 million (M). The FY24 appropriation is \$15M.

The goal of the PCARP is to reduce the burden of pancreatic cancer among Service Members, Veterans, their Families, and the American public. The mission of the PCARP is to promote rigorous, innovative, high-impact research that leads to earlier pancreatic cancer diagnosis, new therapeutic tools, and improved outcomes.

II.A.1. FY24 PCARP Focus Areas

To meet the intent of the funding opportunity, all applications to the FY24 PCARP *must address* at least one of the FY24 PCARP Focus Areas:

- Early detection research for pancreatic cancer, including the prevalence in individuals with pre-diabetes and diabetes and/or those in underserved ethnic and minority communities.
- Supportive care interventions, patient-reported outcomes, quality of life, and perspectives during diagnosis, treatment, and survivorship.
- Barriers to the implementation of healthcare, including ways to overcome socioeconomic, geographic, or ethnic and racial disparities.
- Identification and characterization of pancreatic cancer risk including genetic and environmental risk factors, such as diet, obesity, and microbiome.
- Understanding the relationship between metabolic disruptions in pancreatic cancer and their systemic effects, including diabetes and cachexia.
- Understanding tumor development and progression, from precursors to metastasis
- Understanding the relationship between oncogenic signaling and the tumor microenvironment that drives drug resistance and therapeutic response.
- Biomarkers to predict therapeutic response and guide management strategies.
- New drug development targeted toward cancer sensitivity and resistance mechanisms including immune mechanisms of resistance.

II.A.2. Award History

The PCARP Translational Research Partnership Award mechanism was first offered in FY20. Since then, 69 Translational Research Partnership Award applications have been received, and 14 have been recommended for funding.

II.B. Award Information

The FY24 PCARP Translational Research Partnership Award supports partnerships between clinicians and research scientists that will accelerate the movement of promising ideas in pancreatic cancer toward clinical applications. This award supports the development of translational research collaborations between two independent investigators to address a central problem or question in pancreatic cancer in a manner that would be less readily achievable through separate efforts. One partner in the collaboration *must* function as a research scientist and the other partner as a clinician investigator. It should be clear that both have had equal intellectual input in the design of the research project. *Projects involving convergence science partnerships are strongly encouraged.* At least one partner *must* have expertise either in pancreatic cancer research or pancreatic cancer patient care. Inclusion of experts from outside the pancreatic cancer field is encouraged. A proposed project in which the clinical partner merely supplies tissue samples or access to patients will not meet the intent of this award mechanism. Full support for large-scale clinical trials is not expected; retrospective tissue analysis, correlative studies, or small pilot clinical trials are permitted.

Significant features of the Translational Research Partnership Award:

- **Partnership:** The success of the project should depend on the unique skills and contributions of each partner.
- Translation: The application should provide evidence for the reciprocal transfer of information between basic and clinical science, or vice versa, in developing and implementing the research plan. Translational research may include correlative studies and/or development of or use of annotated biorepositories. The application should demonstrate how the study will leverage clinical information to address knowledge gaps in resulting outcomes, validate key research findings, expand upon potentially transformative results, and/or investigate novel findings.
- **Impact:** The proposed research should indicate the potential to have a significant impact on pancreatic cancer research and/or patient care and have the potential to accelerate the movement of promising ideas (in prevention, diagnosis, detection, prognosis, treatment, and/or survivorship) into clinical applications.
- **Feasibility:** The application should demonstrate that the investigators have access to the necessary specimens, data, and/or intervention, as applicable.
- **Preliminary Data:** Published and/or unpublished results from the laboratory of the Principal Investigators (PIs) or collaborators named on the application that are relevant to pancreatic cancer and the proposed research project, *are required*.

Preliminary data to support the feasibility of the research hypothesis(es) and research approaches are required; however, these data do not necessarily need to be derived from studies of pancreatic cancer.

Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge of patients and anecdotal data. The ultimate goal of translational research is to move a concept or observation forward into clinical application that is relevant to active-duty Service Members, Veterans, other military beneficiaries, and the American public. However, translational research should not be viewed as a one-way continuum from bench to bedside. The research plan must involve a reciprocal flow of ideas and information between basic and clinical science. There should be an intellectual synergistic partnership between the clinic and the laboratory.

The success of the project must be supported by the unique skills and contributions of each partner. The proposed study must include clearly stated plans for interactions between the PIs and the institutions involved. The plans must include communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

The Translational Research Partnership Award requires two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI, refer to Section II.D.2, Content and Form of the Application Submission.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 PCARP priorities.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Rigor of Experimental Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (https://www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public. Collaborations between researchers at military or Veteran institutions and nonmilitary institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the partners bring to the research effort, ultimately advancing cancer research that is of significance to the Warfighter, military Families, and the American public.

Small, pilot clinical trials are permitted under this award mechanism.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

- (1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
- (2) Epidemiologic and behavioral studies that do *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.
- (3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 PCARP Translational Research Partnership Award should not exceed \$750,000. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately \$4.8M to fund approximately four Translational Research Partnership Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and nonprofit organizations, and public entities.

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible *organizations*, not to individuals.

Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

- PIs must be at or above the level of Assistant Professor or equivalent.
- One partner in the collaboration must function as a research scientist and the other as a clinician investigator.
- Clinician investigators must be an M.D., D.O, M.D./Ph.D., or equivalent with clinical duties.

- Postdoctoral and clinical fellows are not eligible.
- At least one member of the partnership *must* have expertise either in pancreatic cancer research or pancreatic cancer patient care.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

The CDMRP strongly encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at https://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access .gov and .mil websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Refer to <u>Section II.H.2</u>, <u>Administrative Actions</u>, for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

II.D.1. Location of Application Package

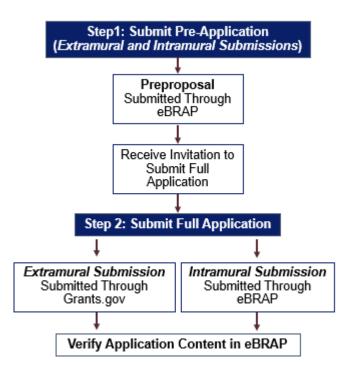
Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an <u>extramural organization</u> for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524PCARPTRPA from Grants.gov (https://grants.gov). Full applications from extramural organizations *must* be submitted through Grants.gov.

Intramural Submission: An application submitted by an <u>intramural DOD organization</u> for an investigator employed by that organization. Intramural DOD organizations <u>may</u> submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524PCARPTRPA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

II.D.2. Content and Form of the Application Submission

Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 PCARP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to <u>Section II.H.2.c</u>, <u>Withdrawal</u>, or contact the eBRAP Help Desk at <u>help@eBRAP.org</u> or 301-682-5507.

II.D.2.a. Step 1: Pre-Application Submission

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for the Partnering PI.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for each PI, the Business Official(s), performing organization(s), and contracting organization(s) must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. *The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.* If not previously registered, the Partnering PI must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to complete these steps as soon as possible. If they are not completed:

- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your pre-application:

Application Proposes:	Select Option:
Preclinical or Translational Research	Translational Research Partnership Award (TRPA)
Pilot Clinical Trial	Translational Research Partnership Award with Pilot Clinical Trial Option (TRPA-PCT)

II.D.2.a.i. Pre-Application Components

• Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

• Preproposal Narrative (two-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- Research Idea: State the hypothesis(es) to be tested or the objective(s) to be reached. State the FY24 PCARP Focus Area(s) that will be addressed. Detail the scientific rationale on which the proposed project is based and briefly describe relevant preliminary data. Concisely state the specific aims and provide a brief overview of the study design. If the proposed research includes a clinical trial, briefly state the clinical intervention, subject population(s), and phase of the clinical trial.
- Partnership: Describe how the collaborative efforts of the PIs will result in a level of productivity that will be greater than that achievable by each PI working independently. Describe how the combined efforts are centered on a unified objective and how the PIs will work together to achieve that objective from different perspectives. Briefly describe the PIs' histories of collaborative study with each other or with other investigators, including the PIs' abilities to function synergistically in a project among equals.
- Impact: Describe the potential impact of this study on the outcomes of individuals with pancreatic cancer, their families/caregivers, and/or the understanding of pancreatic cancer.
- Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application must be uploaded as individual files and are limited to the following:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- Key Personnel Biographical Sketches (five-page limit per individual): All biographical sketches should be uploaded as a single combined file. Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

II.D.2.a.ii. Pre-Application Screening Criteria

- To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the PCARP, pre-applications will be screened based on the following criteria:
 - **Research Idea:** Whether the proposed research addresses one or more of the <u>FY24</u> <u>PCARP Focus Areas</u>. The degree to which the study design for accomplishing the specific aims is feasible, will accomplish the objectives, and is based on sound rationale and preliminary data.
 - **Partnership:** How well the proposed study represents a synergistic collaboration that will produce results greater than those of the PIs working independently. To what degree the combined efforts are centered on a unified objective and demonstrate that the PIs are working together to achieve that objective from different perspectives.
 - o **Impact:** What potential impact this study will have on the outcomes of individuals with pancreatic cancer, their families/caregivers, and/or the understanding of pancreatic cancer.

II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

II.D.2.b. Step 2: Full Application Submission Components for the Initiating PI

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations *must* be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

II.D.2.b.ii. Full Application Submission Components for the Initiating PI

The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. All associated applications (the Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.

Each application submission must include the completed full application package for this program announcement. See <u>Section II.H.3</u> of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form (Extramural Submissions Only): Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

• Attachment 1: Project Narrative (15-page limit): Upload as "ProjectNarrative.pdf". The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application. Describe the proposed project in detail using the outline below.

Outline for projects without a clinical trial:

- Background: Present the ideas and scientific rationale behind the proposed research; include relevant literature citations, preliminary data, and/or preclinical data that led to the development of the proposed study. Any preliminary data provided should be from the laboratory of the PIs or member(s) of the collaborating team.
- Hypothesis(es)/Objective(s): State the hypothesis(es)/study question(s) and/or overall objective(s) to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- Research Strategy and Feasibility: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific evaluation. Include specific examples of synergistic elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE 2.0 (Animal Research: Reporting *In Vivo* Experiments) guidelines (https://arriveguidelines.org/arrive-guidelines). Additionally, describe how the proposed animal studies are designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Where relevant, describe the availability of and access to tissue, data, or human subjects.
- If applicable, describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement.
- **Research Team:** Describe how the combined backgrounds and pancreatic cancer-related experience of the research team will enable successful conduct of the project.
- Project Coordination and Communication: Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among both PIs and institutions participating in the project.
- Data Collection and Statistical Analysis Plan: Describe how data will be collected
 and analyzed in a manner that is consistent with the study objectives. Detail a
 statistical plan for the resulting outcomes. If applicable, include a complete power
 analysis to demonstrate that the sample size is appropriate to meet the objectives of

the study. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. If applicable, describe how data will be appropriately reported and documented to support a regulatory filing with the Food and Drug Administration (FDA).

Outline for projects with a clinical trial:

Note: The Project Narrative is NOT the formal clinical trial protocol. Instead, all elements of the proposed pilot clinical trial necessary for peer review must be described as indicated below.

- Background: Present the scientific rationale behind the proposed research; include relevant literature citations, preliminary data, and/or preclinical data that led to the development of the proposed clinical trial. Any preliminary data provided should be from the laboratory of the PIs or members of the collaborating team.
 - Clearly support the choice of study variables and explain the basis for the study question(s) and/or study hypothesis(es). Establish the relevance of the study and explain the applicability of the proposed findings.
 - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.
- **Hypothesis(es)/Objective(s):** State the hypothesis(es)/study question(s) and overall objective(s) to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- Research Strategy and Feasibility (include only if laboratory research studies are proposed as a component of the application): Describe the laboratory research studies that will be performed under this award and how they are clearly linked to the clinical trial. Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. Where relevant, describe the availability of and access to the requisite data and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the proposed research. Provide a well-developed, well-integrated research strategy that supports the feasibility of the approach. If the methodology is new or unusual, provide sufficient details for evaluation.
- Clinical Trial: Provide detailed plans for initiating, conducting, and completing the clinical trial during the period of performance. As appropriate, briefly outline a plan for obtaining an Investigational New Drug (IND) approval or Investigational Device Exemption (IDE) status (or other FDA approvals). Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed

methodology in sufficient detail to show a clear course of action. Address potential problem areas and present alternative methods and approaches.

- Describe the intervention to be studied, how it will be applied, and the projected outcomes of the study.
- Define the study variables, describe how they will be measured, and include a description of appropriate controls and the endpoints to be tested.
- Describe the availability of and access to critical reagents (e.g., therapeutic molecules) necessary for the clinical trial.
- Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
 Provide information on the availability of and access to sufficient number of subjects for the clinical trial.
- Describe the human subject-to-group assignment process (randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- Describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under "Resources and Reference Material" at https://ebrap.org/eBRAP/public/Program.htm.
- Data Collection and Statistical Analysis Plan: Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Detail a statistical analysis plan for the resulting outcomes. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and lead to meaningful results. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Specify the approximate number of human subjects/samples that will be accrued. If multiple study sites are involved, state the approximate number to be enrolled at each site. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Clinical Team:** Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, statistician) possesses the appropriate experience in conducting clinical trials.

- Project Coordination and Communication: Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among both PIs and institutions participating in the project.
- Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf". Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration: Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."
 - Intellectual and Material Property Plan (*if applicable*): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- DOD Data Management Plan (two-page limit is recommended): Describe the data management plan in accordance with Section 3.c, Enclosure 3, <u>DoD Instructions 3200.12</u>. Do not duplicate the Data and Research Resources Sharing Plan. Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- Plan: Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available.
- Use of DOD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
 - Use of U.S. Department of Veterans Affairs (VA) Resources (*if applicable*): Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated nonprofit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Enrollment Table (if applicable): Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf". The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the scientific rationale behind the proposed work. Identify the FY24 PCARP Focus Area(s) to be addressed in the proposed research.
- **Hypothesis(es)/Objective(s):** State the hypothesis(es) to be tested/objective(s) to be reached. Provide evidence or rationale that supports the hypothesis(es)/objective(s).
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design including appropriate controls.
- Impact: Summarize how the proposed project is relevant to and will have an impact
 on the outcomes of individuals with pancreatic cancer, their families/caregivers,
 and/or the understanding of pancreatic cancer.
- Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf". The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. Abstracts of all funded research projects will be posted publicly. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Do not duplicate the technical abstract.

Lay abstracts should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine*. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

- Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.
- State the <u>FY24 PCARP Focus Area(s)</u> the project addresses.

- Explain the impact that the proposed research project's results might have on the field
 of pancreatic cancer research and/or patient care, including the PCARP's vision of
 diminishing the burden of pancreatic cancer.
- Describe the impact, in the short term or long term, on individuals with pancreatic cancer, their families/caregivers, and/or the understanding of pancreatic cancer.
- Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

For the Translational Research Partnership Award, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.

- Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf". Explain in detail why the proposed research project is important, as follows:
 - Explain how the project addresses one or more of the <u>FY24 PCARP Focus Areas</u> as it relates to the PCARP's goal of diminishing the burden of pancreatic cancer among Service Members, Veterans, their Families, and the American public.
 - **Describe the short-term impact:** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research.
 - Describe the long-term impact: Explain the anticipated long-term gains from the proposed research, including the long-term anticipated advantages that the new understanding may ultimately lead to earlier diagnosis, new therapeutic tools, and improved outcomes in patient care and the elimination of pancreatic cancer.
- Attachment 7: Partnership Statement (one-page limit): Upload as "Partnership.pdf". Discuss in detail how the proposed project is centered on a unified theme that addresses a central problem or question rather than an additive set of unrelated subprojects and the advantages of addressing the research problem through the combined expertise and synergistic efforts of the PIs. Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information (e.g., ongoing communication, decision making, allocation of resources, coordination of research progress and results, and data sharing among all participating PIs and institutions). Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.

Attachment 8: Animal Research Plan (five-page limit): Upload as "AnimalResPlan.pdf". (Attachment 8 is only applicable and required for applications proposing animal studies.)

If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why
 the animal species, strain, and model(s) being used can address the scientific
 objectives and, where appropriate, the study's relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- Attachment 9: Regulatory Strategy (applicable only if proposing a clinical trial; no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".

Describe the regulatory strategy using the following outline and provide supporting documentation as applicable.

State the product/intervention name.

For products/interventions that do not require regulation by the FDA or an international regulatory agency:

For investigator-sponsored regulatory exemptions (e.g., IND, IDE) provide evidence of institutional support. Provide evidence that the clinical trial does not require regulation by the FDA. If the clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this attachment is required.

For products/interventions that require regulation by the FDA or an international regulatory agency:

- State whether the product is FDA-approved, -licensed, or -cleared and marketed in the U.S.
- If the product/intervention has already received FDA approval:
 - Provide a copy of the acceptance letter from the FDA.
 - If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
- If the product/intervention *has not* already received FDA approval:
 - State the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification.
 - Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
 - Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, and the types of FDA meetings that will be held/planned. Include considerations for compliance with current Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines.
- If an IND or IDE application is required to initiate the proposed research project, it must be submitted to the FDA prior to the FY24 PCARP Translational Research Partnership Award application submission deadline. The IND or IDE application should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. Provide the date of submission, application number, and sponsor for any existing FDA applications in place. If there are any existing cross-references in place, provide the application number and associated sponsor. Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, or on clinical hold). Provide a summary of previous meetings with the FDA (or other applicable national regulatory agency) on development of this product, if appropriate. A copy of the agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application. The government reserves the right to withhold or withdraw funding if an IND or IDE application is necessary but has not

been submitted to the FDA or other applicable national regulatory agency by the application submission deadline, or if documented status of the IND or IDE has not been obtained within 9 months of the award date.

- If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).
- If a drug is to be used in the proposed clinical trial, describe the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), nonclinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
- If a device is to be used in the proposed clinical trial, indicate who holds the intellectual property rights to the intervention, if applicable, and how the PIs have obtained access to those rights for the conduct of the clinical trial.
- Attachment 10: Representations (Extramural Submissions Only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/ public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 11: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf". If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The total costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
 - PI Biographical Sketch (five-page limit): Upload as "Biosketch LastName.pdf".

- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".
- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch LastName.pdf".
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support LastName.pdf".
- (e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
 - Budget Justification (no page limit): For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
 - o Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.
- (f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only): Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.
 - Extramural Subaward: Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
 - o Intramural DOD Subaward: Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 11.

II.D.2.b.iii. Full Application Submission Components for the Partnering PI

The application submission process for the Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

(a) SF424 Research & Related Application for Federal Assistance Form (Extramural Submissions Only): Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

(b) Attachments:

- Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Each PI must submit an identical copy of a jointly created SOW.
- Attachment 10: Representations (Extramural submissions only): Upload as "RequiredReps.pdf".
- Attachment 11: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".
- (c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.
- (d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.
 - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf".
 - PI Previous/Current/Pending Support (no page limit): Upload as "Support LastName.pdf".
 - Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch LastName.pdf".
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
- **(e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.
 - Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

The initiating and Partnering PI must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

- (f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only): Refer to the General Application Instructions, Section IV.B.(g), for detailed information.

- Extramural Subaward: Complete the Research & Related Subaward Budget Form through Grants.gov.
- o **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as <u>Attachment 11</u>.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline. Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The combined direct costs budgeted for the entire period of performance should not exceed \$750,000. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 3 years.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

For this award mechanism, direct costs:

Must be requested for:

- Support for multidisciplinary collaborations, including travel.
- Costs for up to two investigators (i.e., one for each PI's budget) to travel to one scientific/technical meeting per year to present project information or disseminate project results from the FY24 PCARP Translational Research Partnership Award.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**, which are of equal importance:

Research Strategy and Feasibility

- How well the scientific rationale for the proposed study and its feasibility are supported by the preliminary data, critical review and analysis of the literature, and/or laboratory and/or preclinical evidence.
- How well the study aims, hypothesis(es) or objective(s), experimental design, methods, and analyses are developed.
- How well the application acknowledges potential problems and addresses alternative approaches.
- If animal studies are included, how well they are designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.

- Whether there is documented availability of and access to quality control for all data and/or critical reagents, and/or cohorts, if applicable.
- o If applicable, how well the plan for the recruitment of subjects or the acquisition of samples is justified and appropriate to accomplish the proposed work.
- o If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

In addition, for those applications selecting the Translational Research Partnership Award with Pilot Clinical Trial Option:

• Whether the proposed laboratory research studies are clearly linked to the proposed clinical trial.

• Clinical Trial (Translational Research Partnership Award with Pilot Clinical Trial Option only)

- Whether the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.
- How well the clinical trial is designed with appropriate study variables, controls, and endpoints.
- Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment is appropriate for the proposed research.
- Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE application status (or other FDA approval), if appropriate.

• Regulatory Strategy (Translational Research Partnership Award with Pilot Clinical Trial Option only)

- How the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.
- Whether the application includes documentation that the study is exempt from FDA regulation or the IND or IDE application has been submitted to the FDA, as appropriate.
- For investigator-sponsored regulatory exemptions (e.g., IND approval, IDE), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
- Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.

• Statistical Plan

• To what degree the statistical plan is appropriate for the experimental and/or clinical methodology being used.

- Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed, if applicable.
- o If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

Impact

- o How well the proposed research addresses at least one of the FY24 PCARP Focus Areas.
- o To what degree the proposed study could, whether in the short term or long term, make a significant impact on pancreatic cancer research and/or patient care, including the PCARP's vision of diminishing the burden of pancreatic cancer.

Personnel

- How the PIs have assembled an appropriate research team with their combined backgrounds and pancreatic cancer-related experience to enable successful conduct of the project.
- o To what degree the proposed partnership between the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.
- Whether the levels of effort are appropriate for successful conduct of the proposed project.
- o To what degree the proposed project is centered on a unified theme that addresses a central problem or question rather than an additive set of unrelated subprojects.
- How well the application addresses processes for ongoing communication, decisionmaking, allocation of resources, coordination of research progress and results, and sharing of data among all participating PIs and institutions.
- o How the partners' combined expertise will better address the research question.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

Environment

- To what extent the scientific environment is appropriate for the proposed research project.
- How well the research requirements are supported by the availability of and access to facilities and resources.
- To what degree the quality and extent of institutional support are appropriate for the proposed research.

• If multi-institutional, to what degree the intellectual and material property plan is appropriate.

Budget

- Whether the direct costs exceed the allowable direct costs as published in the program announcement.
- Whether the budget is appropriate for the proposed research.

• Application Presentation

o To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 PCARP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity
 - Program portfolio balance
 - o Programmatic relevance to FY24 PCARP Focus Areas
 - Partnership and Synergy
 - Relative impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in <u>Section II.E.1.b</u>, <u>Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.*

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the PCARP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to *intragovernmental and intramural DOD organizations* will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> <u>Terms and Conditions</u>: <u>Addendum to the DoD R&D Terms and Conditions</u> for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Inclusion Enrollment Reporting: *(only required for clinical research studies and pilot clinical trials)*: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity using the PHS Inclusion Enrollment Report will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as

specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: <u>help@eBRAP.org</u>

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of pre-applications or full applications, the following administrative actions may occur.

II.H.2.a. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.

- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the full application:

- An FY24 PCARP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation.
 A list of the FY24 PCARP Programmatic Panel members can be found at https://cdmrp.health.mil/pcarp/panels/panels24.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The invited application proposes a different research project than that described in the preapplication.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not address at least one of the <u>FY24 PCARP Focus Areas</u>.
- The research proposed is not based on preliminary data.
- Proof of submission to the FDA is not provided at the award application submission deadline if an IND or IDE application is required to initiate the proposed TRPA research project.
- The Initiating PI or Partnering PI does not meet the eligibility criteria.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Full Application Submission Checklist

	Uploaded	
Full Application Components	Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance (Extramural submissions only)		
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)		
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"		
Supporting Documentation – Attachment 2, upload as "Support.pdf"		
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"		
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"		
Statement of Work – Attachment 5, upload as "SOW.pdf"		
Impact Statement – Attachment 6, upload as "Impact.pdf"		
Partnership Statement – Attachment 7, upload as "Partnership.pdf"		
Animal Research Plan – Attachment 8, upload as "AnimalResPlan.pdf"		
Regulatory Strategy – Attachment 9, upload as "Regulatory.pdf"		
Representations (Extramural submissions only) – Attachment 10, upload as "RequiredReps.pdf"		
Suggested Intragovernmental Budget Form (if applicable) – Attachment 11, upload as "IGBudget.pdf"		
Research & Related Personal Data		
Research & Related Senior/Key Person Profile (Expanded)		
Attach PI Biographical Sketch (Biosketch_LastName.pdf)		
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)		
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person		
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person		
Research & Related Budget (Extramural submissions only) Include budget justification		

Budget (Intramural submissions only) Include budget justification	
Project/Performance Site Location(s) Form	
Research & Related Subaward Budget Attachment(s) Form (if applicable)	

APPENDIX 1: ACRONYM LIST

ARRIVE Animal Research: Reporting In Vivo Experiments

ACOS/R&D Associate Chief of Staff for Research and Development
CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations
DHP Defense Health Program
DOD Department of Defense

DoDGARs Department of Defense Grant and Agreement Regulations

eBRAP Electronic Biomedical Research Application Portal

ET Eastern Time

FAD Funding Authorization Document FDA Food and Drug Administration

FY Fiscal Year

GCP Good Clinical Practice
GLP Good Laboratory Practice
GMP Good Manufacturing Practice

IACUC Institutional Animal Care and Use Committee

IDE Investigational Device Exemption

IND Investigational New Drug
IRB Institutional Review Board

M Million
MB Megabytes

MIPR Military Interdepartmental Purchase Request

OHRO Office of Human Research Oversight (previously Human Research Protection

Office)

ORCID Open Researcher and Contributor ID, Inc.

PCARP Pancreatic Cancer Research Program

PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

RPPR Research Performance Progress Report

SAM System for Award Management

SOW Statement of Work

TRPA Translational Research Partnership Award

TRPA-PCT Translational Research Partnership Award with Pilot Clinical Trial Option

UEI Unique Entity Identifier
URL Uniform Resource Locator

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USC United States Code

VA U.S. Department of Veterans Affairs