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

Idea Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524PCARPIDA

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."

TABLE OF CONTENTS

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 health care, 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 Idea Development Award mechanism was first offered in FY20. Since then, 194 Idea Development Award applications have been received, and 46 have been recommended for funding.

II.B. Award Information

The PCARP Idea Development Award supports the development of innovative, high-risk/high-reward research that could lead to critical discoveries or major advancements that will accelerate progress in improving outcomes for individuals with pancreatic cancer. This award mechanism is designed to support innovative ideas with the potential to yield impactful data and new avenues of investigation.

Significant features of the Idea Development Award:

- **Impact:** The proposed research is expected to make an important and original contribution to advancing the understanding of pancreatic cancer and ultimately lead to improved outcomes for individuals with pancreatic cancer. The project's impact on both pancreatic cancer research and patient care should be articulated, even if clinical impact is not an immediate outcome.

- **Innovation:** Research deemed innovative may represent a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other highly creative qualities. Research may be innovative in study concept, research methods or technology, or adaptations of existing methods or technologies. Research that represents an incremental advance on previously published work is not considered innovative.

- **Personnel:** Personnel are considered a crucial element of the FY24 PCARP Idea Development Award. At least one member of the research team should have experience in pancreatic cancer research, as demonstrated by recent publications and funding. Inclusion of a biostatistician in the study team is encouraged.

- **Research must be based on preliminary data:** Although the proposed research must have direct relevance to pancreatic cancer, the required preliminary data, which may include unpublished results from the laboratory of the Principal Investigator(s) (PI[s]), research team, or collaborators named on the application, may be from outside the pancreatic cancer research field. Research should also be based on a sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.

Partnering PI Option for Early-Career Investigator: The FY24 Idea Development Award mechanism is offering a higher level of funding for applications that propose to partner an experienced PI (i.e., Initiating PI, who will serve as the mentor) with an Early-Career Investigator (i.e., Partnering PI) wishing to pursue a career in pancreatic cancer research. The

Initiating PI on the Idea Development Award must mentor and collaborate with the Early-Career Investigator (Partnering PI) to promote their career development in pancreatic cancer research. The Early-Career Investigator must meet the specific eligibility criteria described in Section II.C, Eligibility Information. The Initiating PI will be responsible for the majority of the administrative tasks associated with application submission. The Initiating and Partnering PIs each have different submission requirements, as described in Section II.D.2, Content and Form of the Application Submission; however, both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named to an individual award within the recipient organization. ***Projects involving convergence science partnerships are encouraged.***

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.

Clinical trials are not allowed 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 Idea Development Award should not exceed **$500,000.** The anticipated direct costs budgeted for the entire period of performance for an FY24 PCARP Idea Development Award – Partnering PI Option for Early Career Investigator should not exceed **$650,000**. 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 $7.36M to fund approximately four Idea Development Award – Single PI applications and four Idea Development Award – Partnering PI Option for Early Career Investigator 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

For Single PI applications:

- Investigators must be at or above the level of Assistant Professor (or equivalent) to be named by the organization as the PI on the application.

For application submissions under the Partnering PI Option for Early-Career Investigator:

- The Initiating PI (mentor) must be at or above the level of Assistant Professor (or equivalent) to be named by the organization as the PI on the application.
- By the full application submission date, the Partnering PI (Early-Career Investigator) must:
    - Have instructor-level (or equivalent) faculty appointment or above.
    - Be no more than 10 years from the receipt of a terminal degree (excluding time spent in residency or on family medical leave) at the time of the application deadline.

- It is not required that the Partnering PI (Early-Career Investigator) and the Initiating PI (mentor) be located at the same institution.

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 Section II.H.2, Administrative Actions, 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

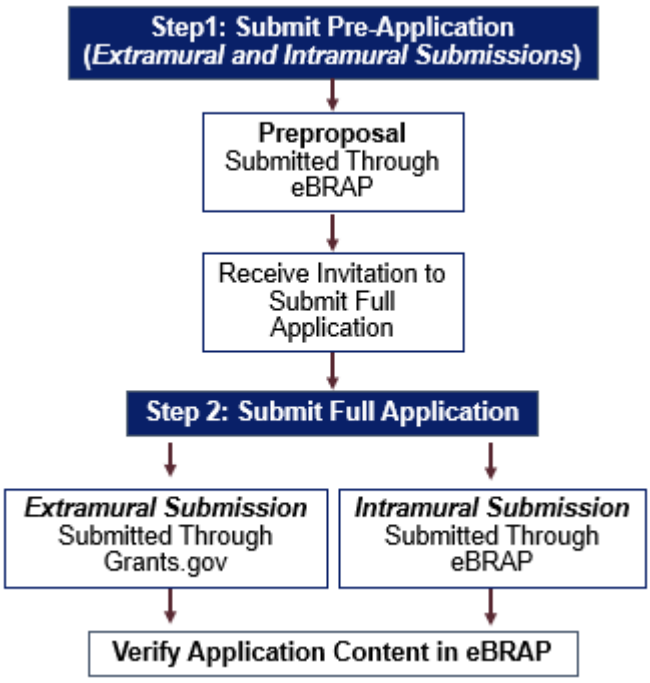
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the 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 extramural organization 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 HT942524PCARPIDA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524PCARPIDA 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 Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

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.

Partnering PI Option for Early-Career Investigator: 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 Includes:	Select Option:
Single PI	Idea Development Award (IDA)
Initiating PI and Partnering PI	Idea Development Award – Partnering PI Option for Early-Career Investigator (IDA-PPIO)

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 (Single PI submission: two-page limit; Partnering PI Option for Early-Career Investigator: three-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 to be tested or the objective 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. Describe how the research study will be accomplished in the defined study population, if applicable. Concisely state the specific aims and provide a brief overview of the study design. ***This award cannot be used to conduct clinical trials or proof-of-concept intervention studies on human subjects.***

- **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.

- **Innovation:** Describe how the proposed project is innovative and how the research represents more than an incremental advance on published data.

- **Personnel:** Clearly describe the pancreatic cancer experience of the proposed research team and how this will factor into the team's ability to successfully complete the project.

- **Partnering PI Option for Early-Career Investigator (if applicable):** Describe how the Initiating PI (mentor) is positioned to provide the Partnering PI (Early-Career Investigator) with mentorship toward a successful career in pancreatic cancer research. Briefly describe the Researcher Development Plan and how it will contribute to fostering the Partnering PI's career development as a pancreatic cancer researcher.

- **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 FY24 PCARP Focus Areas. How well the scientific rationale, preliminary data, study design, and specific aims support the project's objective. To what extent the research can be accomplished with the defined study population, if applicable.

- **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.

- **Innovation:** To what extent the research is innovative and represents more than an incremental advance on published data.

- **Personnel:** To what degree the PI(s) and research team's backgrounds and pancreatic cancer-related experience are appropriate to successfully carry out the proposed research project.

- **Partnering PI Option for Early-Career Investigator (if applicable):** How well the Researcher Development Plan will contribute to fostering the Early-Career Investigator's development as a pancreatic cancer researcher. To what degree the Initiating PI (mentor) is positioned to mentor the Early-Career Investigator toward a successful career in pancreatic cancer research.

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

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 PI or Initiating PI

Partnering PI Option for Early-Career Investigator: 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 Section II.H.3 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 (eight-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.

  - **Background:** Present the scientific rationale behind the proposed research and include relevant literature citations. Describe and show the preliminary data to justify the rationale for the proposed project.

  - **Hypothesis(es) or Objective(s):** State the hypothesis(es) to be tested or the objective(s) to be reached.

  - **Specific Aims:** Concisely explain the project's specific aims to be supported by this application. If the proposed research is correlated with a larger study, present only tasks that this award would fund.

- **Research Strategy/Scientific Merit:** Describe the experimental design, methods, and analyses including appropriate controls, in sufficient detail for assessment. Address potential limitations and present alternative methods and approaches. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis. Describe how the statistical plan is appropriate for the experimental methodology being used. Explain how the proposed statistical analysis supports the relevance of any research outcomes to the FY24 PCARP Focus Area(s). If animal studies are proposed, the applicant is required to submit an Animal Research Plan (Attachment 8). If applicable, describe how the human subject population (clinical trials are not allowed) is appropriate for the study. 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 appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and/or ethnic group, and an accompanying rationale for the selection of subjects. 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 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 *(if applicable)*:** 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, DoD Instructions 3200.12. ***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.

- **Data and Research Resources Sharing 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 IRB review) are exempt from this requirement.

The following supporting documents are required only for application submission under the ***Partnering PI Option for Early-Career Investigator:***

- **Transcripts:** Include a copy of the Trainee's transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the "Full Announcement" page in Grants.gov) in place of the transcript.

- **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 research. Identify the FY24 PCARP Focus Area(s) to be addressed in the proposed research.
- **Hypothesis/Objective:** State the hypothesis to be tested or objective to be reached.
- **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.
- **Innovation:** Briefly describe how the proposed project uses innovation to yield critical discoveries, new avenues of investigation, or major advancements to improve the understanding of pancreatic cancer and ultimately to improve outcomes of individuals with 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.

  - Identify the FY24 PCARP Focus Area(s) to be addressed in the proposed research.
  - Describe the innovative aspects of the proposed research project.
  - 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 Idea Development Award, refer to the "Example: Assembling a Generic Statement of Work" 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".** Summarize how the project addresses one or more of the FY24 PCARP Focus Areas. Describe how the anticipated short-term outcomes of the project will advance the field and may impact those with pancreatic cancer. Describe how the project has the potential to lead to advancements in pancreatic cancer research or improved health outcomes or quality of life for individuals with pancreatic cancer in the short term and/or long term.

- **Attachment 7: Innovation Statement (one-page limit): Upload as "Innovation.pdf".** Summarize how the proposed research is innovative. State how the research challenges existing paradigms or presents new paradigms, technologies, evidence-based diagnoses, and/or applications in the field of pancreatic cancer research. Describe how the proposed research represents more than the next logical step or an incremental advance on published data.

- **Attachment 8: Animal Research Plan (three-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 (Animal Research: Reporting *In Vivo* Experiments) 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: Accomplishments Statement (four-page limit): Upload as "Accomplishments.pdf".** Provide pancreatic cancer or other cancer research accomplishments of the PI, Initiating PI, and/or Partnering PI (if applicable) based on the outline below:

  - Past and current pancreatic cancer or other cancer research support from both federal and nonfederal sources (as applicable) from the past 5 years.

  - Any pancreatic cancer or other cancer publications from the past 5 years.

  - Any honoraria, awards, or other distinctions received for work in pancreatic cancer or other cancer research from the past 5 years.

  - Any patents or other pancreatic cancer or other cancer research accomplishments from the past 5 years.

- **Attachment 10: Data and Research Resources Sharing Plan: Upload as "ResourceSharing.pdf".** Describe how data and resources generated during the performance of the project will be shared with the research community. Specifically describe a plan to make animal models, tissue samples, and other resources developed as part of the proposed research project available to the scientific community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 11: Early-Career Investigator Statement, if applicable (required for Partnering PI Option for Early-Career Investigator; one page recommended): Upload as "ECIStatement.pdf".** The Early-Career Investigator Statement is expected to be written by the Partnering PI (Early-Career Investigator) while also showing evidence of appropriate direction from the Initiating PI, who will serve as the mentor for this project.

  - The Early-Career Investigator should describe their accomplishments (i.e., academic performance, awards, honors, and/or previous publications and funding) and how they are indicative of potential for a successful, productive, independent career in pancreatic cancer research.

  - The Early-Career Investigator should describe their career goals and how the proposed research project and mentored research experience will promote their career development in pancreatic cancer. The Early-Career Investigator should discuss their career/research plans after the completion of this award.

- **Attachment 12: Researcher Development Plan, if applicable (required for Partnering PI Option for Early-Career Investigator; two pages recommended): Upload as "ResearcherDevPlan.pdf"**. The Researcher Development Plan is expected to be written by the Initiating PI (mentor) and articulate the following:

  - Clearly describe and outline the individualized Researcher Development Plan, including proposed training to support the development of the Early-Career Investigator's research skills. If the mentor and Early-Career Investigator are located in the same laboratory, provide a plan that will provide a pathway of independence for the Early-Career Investigator.

  - Highlight the unique features of this plan as it pertains specifically to pancreatic cancer research.

  - Clearly articulate a strategy for the Early-Career Investigator to develop the necessary skills, competence, and expertise to pursue a promising career in pancreatic cancer research.

  - Describe how the Initiating PI is positioned to mentor the Early-Career Investigator toward a successful career in pancreatic cancer research.

  - Describe how the Researcher Development Plan is supported by the research environment, including a description of ongoing pancreatic cancer research at the institution(s). Include information on collaborations with other investigators.

  - Describe the Early-Career Investigator's role in the proposed research project.

- **Attachment 13: Letter of Eligibility, if applicable (required for Partnering PI Option for Early-Career Investigator; one-page limit): Upload as "Eligibility.pdf".** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official to verify that the eligibility requirements have been met. The letter should verify that the Partnering PI is no more than 10 years from their terminal degree (Refer to Section II.C, Eligibility Information). Include the organizational commitment for independent laboratory space (if applicable).

- **Attachment 14: 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 15: 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.
- ***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.

- **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 15.

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 14: Representations *(Extramural submissions only)*: Upload as "RequiredReps.pdf".**

- **Attachment 15: 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 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 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):** 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.

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.

- **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 Attachment 15.

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.

Application submissions with a Single PI: The application's direct costs budgeted for the entire period of performance should not exceed **$500,000**. 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.

Application submissions with the Partnering PI Option for Early-Career Investigator: The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$650,000**. 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.

Any application that requests the higher level of funding and that does not include a partnering PI will have its budget reduced as appropriate.

For this award mechanism, direct costs:

May be requested for:

- Travel in support of multidisciplinary collaborations.
- Travel costs for one investigator to travel to one scientific/technical meeting per year to present project outcomes or disseminate project results for the FY24 PCARP Idea Development Award.

Must not be requested for:

- Clinical trial costs

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:

Note that high innovation and impact do not compensate for deficiencies in scientific merit.

- **Scientific Merit**
    - To what extent a clear hypothesis is stated and supported through scientific rationale, preliminary data, and referenced literature.
    - How well the hypothesis or objectives, specific aims, and experimental design are developed.
    - How well the study is designed to achieve the research objectives, including, if applicable, the development and use of animal model(s) and to what extent the chosen animal and endpoints/outcome measures are justified.
    - If applicable, to what extent the human subject population is appropriate for the study and whether there is clear access to the designated population.
    - How well the application acknowledges potential limitations and addresses alternative methods and approaches.
    - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment is appropriate for the proposed research.

- How well the animal study (or studies, *if applicable*) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
- How well the study (or studies, if *applicable*) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

- **Impact**
  - How well the proposed research addresses at least one of the FY24 PCARP Focus Areas.
  - To what extent the anticipated short-term outcome(s) of the project may impact individuals with pancreatic cancer, and/or improve understanding of pancreatic cancer.
  - To what degree the anticipated short-term and/or long-term gains from this research project may impact the pancreatic cancer community.
  - To what extent the proposed project will ultimately improve the health outcomes or quality of life of individuals with pancreatic cancer.
- **Innovation**
  - To what extent the proposed research is innovative and will challenge existing paradigms, or provide new paradigms, technologies, evidence-based diagnoses, and/or applications for pancreatic cancer.
  - To what degree the proposed research represents more than a logical step and/or incremental advance upon published data.
- **Statistical Plan**
  - To what degree the statistical plan is appropriate for the experimental methodology being used.
  - How well the proposed statistical analysis supports the relevance of any research outcomes to the FY24 PCARP Focus Area(s).
  - Whether the power analysis for the proposed study adequately represents an assessment of the population proposed, if applicable.
- **Personnel**
  - To what extent the research team's background and experience are appropriate to accomplish the proposed research.
  - To what extent each PI's experience and skill in the research areas of pancreatic cancer or other fields have been demonstrated as evidenced by publications, funding, distinctions, awards, and/or patents.

The following separately scored criteria evaluate only the merits of the proposed Partnering PI (Early-Career Investigator). These criteria are considered independent components of the application evaluation and will be considered at the programmatic review to make funding recommendations for applications submitted under the Partnering PI Option for Early-Career Investigator:

- **Early-Career Investigator**
    - To what extent the Partnering PI's (Early-Career Investigator's) achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate potential for a successful career as a pancreatic cancer researcher.
    - To what extent the Early-Career Investigator's stated career goals will promote their career development in pancreatic cancer research.
- **Researcher Development Plan**
    - How well the application has outlined a detailed, individualized Researcher Development Plan that will effectively support the development and, if located in the same laboratory, a pathway for independence of the Early-Career Investigator's research skills in pancreatic cancer research.
    - To what degree the Initiating PI's (mentor's) experience in pancreatic cancer research and mentoring, as demonstrated by a record of active funding, recent publications, and successful mentorship, positions them to mentor the Early-Career Investigator toward a successful career in pancreatic cancer research.
    - To what extent the scientific environment is appropriate for the proposed career development activities

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**
    - Whether the scientific environment is appropriate for the proposed research.
    - Whether the research requirements are supported by the availability of and access to facilities and resources.
    - To what extent the quality and level of institutional support are appropriate for the proposed research.
- **Budget**
    - Whether the maximum **direct** costs are equal to or less than the allowable maximum direct costs as published in the program announcement.

- Whether the budget is appropriate for the proposed research.
- If applicable for the Early-Career Investigator Option, whether appropriate justification is provided by the Initiating PI requesting greater than 50% of the direct cost budget.

- **Application Presentation**
  - 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
  - Programmatic relevance to the FY24 PCARP Focus Areas
  - Relative impact and innovation

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 Section II.E.1.b, Programmatic Review.*** 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 (Early-Career Investigator) is discouraged and will be evaluated on a case-by-case basis.

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 DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions 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.

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.

PHS Inclusion Enrollment Reporting Requirement ***(Required for clinical research and clinical trials)***: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity 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: help@eBRAP.org

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 is missing.

The following will result in administrative rejection of the full application:

- Submission of an application for which a letter of invitation was not issued.
- 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 pre-application.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial or proof-of-concept intervention studies on human subjects is proposed.
- The application does not address at least one of the FY24 PCARP Focus Areas.
- The research proposed is not based on preliminary data.
- The PI (Single, Initiating [mentor], or Partnering [Early-Career Investigator]) 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

Full Application Components	Uploaded	
	Single or 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"	☐	
Innovation Statement – Attachment 7, upload as "Innovation.pdf"	☐	
Animal Research Plan – Attachment 8, upload as "AnimalResPlan.pdf"	☐	
Accomplishments Statement – Attachment 9, upload as "Accomplishments.pdf"	☐	
Data and Research Resources Sharing Plan – Attachment 10, upload as "ResourceSharing.pdf"	☐	
Early-Career Investigator Statement – Attachment 11, upload as "ECIStatement.pdf"	☐	
Researcher Development Plan – Attachment 12, upload as "ResearcherDevPlan.pdf"	☐	
Letter of Eligibility – Attachment 13, upload as "Eligibility.pdf"	☐	
Representations *(Extramural submissions only)* – Attachment 14, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental Budget Form *(if applicable)* – Attachment 15, 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

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
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IDA	Idea Development Award
IDA-PPIO	Idea Development Award – Partnering PI Option for Early-Career Investigator
IRB	Institutional Review Board
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
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
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