I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Data Science Award

Announcement Type: Initial

Funding Opportunity Number: HT942524PCRPDSA

**Assistance Listing Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), August 9, 2024

- **Application Submission Deadline:** 11:59 p.m. ET, August 30, 2024

- **End of Application Verification Period:** 5:00 p.m. ET, September 4, 2024

- **Peer Review:** November 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) Prostate Cancer Research Program (PCRP) 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 PCRP in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY23 totaled $2.26 billion. The FY24 appropriation is $110.0 million (M).

The PCRP seeks to promote highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; the next generation of prostate cancer investigators through mentored research; and resources that will facilitate translational research.

II.A.1. FY24 PCRP Overarching Challenges

The mission of the FY24 PCRP is to fund research that will eliminate death and suffering from prostate cancer and enhance the well-being of Service Members and their Families, Veterans, and all the patients and caregivers who are experiencing the impact of the disease. Within this context, the PCRP is interested in supporting research that addresses specific gaps in prostate cancer research and clinical care; therefore, applications are *required* to address one or more of the following FY24 PCRP Overarching Challenges:

- **Improve quality of life to enhance outcomes and overall health and wellness for those impacted by prostate cancer**

  Applications should aim to understand the impact of prostate cancer on the quality of life of the cancer survivor, their family, their caregivers, and their community with the goal of improving and enhancing quality of life and overall health and wellness. Studies should consider both short- and long-term quality-of-life outcomes. Areas of particular interest include:

  ○ The mental and emotional health of patients and their families/caregivers

  ○ Impact of quality-of-life considerations on decision-making after diagnosis and/or treatment

  ○ Identification of vulnerable groups of patients and their families at great risk of quality-of-life detriments

  ○ Implementation of factors or interventions that improve access to evidence-based care, quality-of-life outcomes, and overall health and wellness

- **Develop new treatments or improve upon existing therapies to improve outcomes for patients with lethal prostate cancer**

  Applications must be directly related to prostate cancer with a high risk of death, including high-risk, localized disease, regional disease, and/or metastatic prostate cancer.

  Treatments may address any stage in the continuum of care, including local therapies such as surgery or radiation designed to treat patients with a high risk of death from the disease. Proposed treatments are highly encouraged to consider preserving patient quality of life and not focus only on survival outcomes.

  Applications should not focus on active surveillance, low-risk and intermediate-risk prostate cancer, and/or biochemical recurrence. Refer to the National Comprehensive Cancer Network guidelines for risk assessment definitions (https://www.nccn.org/patients/guidelines/content/PDF/prostate-advanced-patient.pdf).

- **Advance health equity and reduce disparities in prostate cancer**

  Applications must be directly relevant to better understanding and/or reduction of health inequities and disparities that impact a person, their family, or their caregiver's ability to prevent, detect, manage, and/or survive prostate cancer.

  Applications are encouraged to focus on implementing factors or interventions with the potential to improve access to evidence-based care, quality-of-life outcomes, and overall health and wellness.

  Health equity-focused applications will propose research on how patients can attain full potential for health and well-being, taking into consideration physical, mental, or emotional health differences; the impact of race or ethnicity, geography, and environment; as well as lifestyle and socioeconomic differences experienced in high-risk and/or underserved prostate cancer patient populations.

  High-risk and/or underserved populations include, but are not limited to, people of African descent (including Caribbean), genetically predisposed populations, Service Members, Veterans, patients with limited access to clinical care and resources (in rural or urban settings), or other populations experiencing barriers to quality healthcare.

- **Define the biology of prostate cancer progression to lethal prostate cancer to reduce death**

  Applications must be directly related to high-risk, very high-risk, and metastatic prostate cancer. The FY24 PCRP also strongly encourages research involving patient-derived materials or specimens related to ongoing or completed clinical trials. Refer to the National Comprehensive Cancer Network guidelines for risk assessment definitions (https://www.nccn.org/patients/guidelines/content/PDF/prostate-advanced-patient.pdf).

II.B. Award Information

The FY24 PCRP Data Science Award mechanism supports research where quantitative and analytical approaches, processes, and/or systems are developed and/or used to obtain knowledge and insight from large and/or complex sets of prostate cancer data. If successful, the studies will enable progress toward addressing one or more of the FY24 PCRP Overarching Challenges. It is expected that any resources, tools, or computational processes generated by this award will be openly shared with the prostate cancer research and patient community. This mechanism is intended to fund research built upon the logic, concepts, and methods of one or more of the following research areas as they pertain to prostate cancer:

- Computational biology

- Bioinformatics

- Artificial intelligence and machine learning

- Epidemiology

- Analysis of –omics data

- Medical imaging

- Digital pathology

- Analysis of other clinically annotated datasets

Applications may combine diverse data types for integrative analysis to increase knowledge about prostate cancer with respect to the FY24 PCRP Overarching Challenges. Applications that propose to develop resources or tools that allow research, clinical care, and patient community access to standardized and harmonized datasets for real-time clinical care applications are of particular interest; however, *this award must not be used to support the development of new datasets.* Studies utilizing data derived from large patient studies that include long-term health records or repositories with well-annotated and high-quality biospecimens are encouraged.

Key Features:

- **Research Approach:** Applications may propose development of a new data-science-driven tool or apply an existing tool or method to gather and analyze information from large datasets with the intent of advancing prostate cancer research and patient care relative to the FY24 PCRP Overarching Challenges. *Inclusion of preliminary data to support the scientific rationale and feasibility of research approaches is strongly encouraged, but not required.* Any preliminary data provided should be from the laboratory of the Principal Investigator(s) (PI[s]) or member(s) of the collaborating team. Applicants are encouraged to include plans for rigorous validation, benchmarking, comparisons, and/or evaluations to assess the quality or utility of the tools and/or approaches that will be used or developed under this award. Any datasets used in the study design must be from established, retrospective databases and be sufficient in size to provide appropriate analytical and statistical power. *Prospective*

recruitment of human subjects and/or clinical trials is not allowed under this funding opportunity. Applicants are expected to provide documentation demonstrating access to the appropriate datasets and/or patient samples in numbers sufficient to achieve robust results.

- **Impact:** Applications are required to clearly communicate how the proposed quantitative and/or analytical approaches, processes, and/or systems will address and provide a solution to one or more of the FY24 PCRP Overarching Challenges. The potential impact of the research, both short- and long-term, should be clearly described, including how the anticipated outcomes or products are distinct from existing research efforts in this area and/or how they will significantly outperform current approaches in this area. High-impact research will, if successful, significantly advance prostate cancer research and/or patient care.

- **Data and Resource Sharing Plan:** It is expected that any resources, tools, and computational processes that are developed under this award will be openly shared with the prostate cancer research and patient community. Plans must be provided for how additional data generated by future studies will be incorporated to further inform and refine the data science tools, processes, and/or methods generated and/or used in this study. Refer to the CDMRP's Policy on Data & Resource Sharing located on the Electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about the CDMRP's expectations for making data and research resources publicly available.

Partnering PI Option: The FY24 PCRP Data Science Award encourages applications that include meaningful and productive collaborations between investigators. The PIs may have expertise in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application; ***collaborations between data scientists and clinicians are highly encouraged***. The Partnering PI Option is structured to accommodate 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, including the Project Narrative, Statement of Work (SOW) and other required components. If recommended for funding, each PI will be named on separate awards to the recipient organization. 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, the 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 PCRP 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.

Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

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 (http://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.

Clinical trials are not allowed. 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 PCRP Data Science Award should not exceed **$1.0M**. 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 $11.2M to fund approximately seven Data Science 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 non-profit 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

Each investigator may be named on only one FY24 PCRP Data Science Award application as a PI, Initiating PI, or Partnering PI.

Independent investigators at all levels are eligible to be named as a PI, Initiating PI, or Partnering PI on an application for the FY24 PCRP Data Science Award.

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

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 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

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┌──────────────────────────────────────────┐
│     Step1: Submit Pre-Application          │
│ (Extramural and Intramural Submissions)    │
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       │      Letter of Intent      │
       │    Submitted Through       │
       │          eBRAP            │
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       │ Step 2: Submit Full Application │
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  │ Extramural Submission │  │ Intramural Submission │
  │  Submitted Through    │  │  Submitted Through    │
  │     Grants.gov        │  │        eBRAP          │
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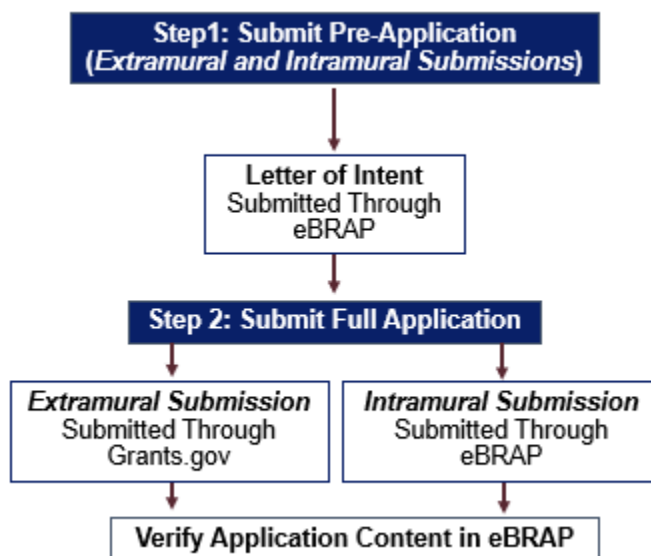
Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524PCRPDSA 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 HT942524PCRPDSA 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 the 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 PCRP 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.

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: 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.

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.

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	No Option
Partnering PI	Partnering PI

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 detailed instructions regarding pre-application submission):

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY24 PCRP Overarching Challenge under which the application will be submitted.

  LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

II.D.2.b. Step 2: Full Application Submission

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: 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 (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. ***Inclusion of preliminary data to support the scientific rationale and feasibility of research approaches is strongly encouraged, but not required.*** Any preliminary data provided should be from the laboratory of the PI(s) or member(s) of the collaborating team.

– **Background:** Present the ideas and reasoning behind the proposed research and the FY24 PCRP Overarching Challenges that will be addressed. The application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature; include relevant literature citations and preliminary and/or preclinical data (if applicable) that led to the development of the proposed study. Describe previous experience of the research team most pertinent to this application, including examples of previous successful collaborations (if applicable).

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

- **Specific Aims:** Concisely explain the project's specific aims to be funded by this application. If this application is part of a larger study, present only tasks that this award would fund. The specific aims should be aligned with the specific aims/tasks outlined in the SOW.

- **Research Strategy and Feasibility:**

  - Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. If applicable, describe plans for rigorous validation, benchmarking, comparison, and/or evaluation to assess the quality or utility of the proposed tool(s) and/or approach(es).

  - Include a description of resources needed to support the project (databases, biospecimens, cohorts, etc.). Indicate whether the resources are readily available and/or provide a plan for acquiring any resources that are not readily available; explain how these resources will be sufficient to achieve robust statistical significance. For clinical research, see Attachment 9 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study. ***Prospective recruitment of human subjects and/or clinical trials is not allowed under this funding opportunity.***

  - Address potential problem areas and present alternative methods and approaches.

- **Statistical Plan:** Clearly describe the statistical plan and the rationale for the statistical methodology. Include sample size projections and an appropriate power analysis, if applicable. Describe the biostatistical expertise that will be available to support the analysis(es).

If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to the General Application Instructions, Appendix 4, for additional considerations.

○ **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.

– **Letters of Support (if applicable):** Provide a signed letter from any organizations providing resources (e.g., long-term health records, repositories with well-annotated and high-quality biospecimens, datasets) for the proposed study that will demonstrate that the PI(s) have the support and access to resources necessary for the proposed work.

– **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.

– **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](https://ebrap.org). ***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 the 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 the 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 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 non-profit 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.

○ **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.

Programmatic reviewers typically do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

Describe the proposed research project including the following elements:

- **Background:** Present the scientific rationale behind the proposed research project.

- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached. Provide evidence or rationale that supports the objective/hypothesis.

- **Specific Aims:** State the specific aims of the study.

- **Study Design:** Describe the study design, including appropriate controls.

- **Impact:** Summarize the potential near-term and long-term impact of the proposed research. Include how the anticipated outcomes will provide a foundation for future research projects that will enable progress towards a solution to one or more of the FY24 PCRP Overarching Challenges and ultimately make a major impact toward eliminating death and suffering from prostate cancer and enhancing the well-being of Service Members and their Families, Veterans, and all the patients and caregivers who are experiencing the impact of the disease.

○ **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 ultimate applicability of the research.

- What are the likely contributions of this study to the FY24 PCRP Overarching Challenges?

- What types of patients will it help and how will it help them?

- What are the potential clinical applications, benefits, and risks?

- What is the projected time it may take to achieve a patient-related outcome?

- If the research is too basic for clinical applicability, describe the interim outcomes

○ **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 Data Science Award mechanism, 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.

○ **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".**

Explain in detail why the proposed research project is important, as follows:

– ***Describe the short-term impact:*** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research, including any clinically relevant results. Summarize how the anticipated outcome(s)/product(s) are distinct from existing research efforts in this area and/or how they will significantly outperform current approaches. Summarize how the anticipated outcome(s)/ product(s) will provide a foundation for future research projects that will enable progress toward a solution to one or more of the FY24 PCRP Overarching Challenges.

– ***Describe the long-term impact:*** Explain the anticipated long-term gains from the proposed research. Describe how the anticipated long-term gains would make an impact on prostate cancer patient care and ultimately contribute to the goal of eliminating death from prostate cancer and enhancing the well-being of Service Members and their Families, Veterans, and all the patients and caregivers who are experiencing the impact of the disease.

○ **Attachment 7: Partnership Statement (one-page limit): Upload as "Partnership.pdf". *(Attachment 7 is only applicable and required for applications submitted under the Partnering PI Option.)*** Describe the expertise of the Initiating and Partnering PIs. Describe the contribution and the time commitment of each PI toward the proposed research project. Describe how the partners' combined expertise will better address the research question and explain why the work should be done together rather than through separate efforts.

○ **Attachment 8: Transition Plan (one-page limit): Upload as "Transition.pdf"**. Provide information on potential methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award (e.g., specific potential industry partners, specific funding opportunities to apply for). If the application does not include a clinical trial, provide a realistic timeline for near-term clinical investigation. In addition, provide a plan to distribute the findings or intervention to the prostate cancer community.

○ **Attachment 9: Inclusion of Women and Minorities (four-page limit): Upload as "Inclusion.pdf". *(Attachment 9 is only applicable and required for applications that propose clinical research.)*** 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 ethnic group and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The PHS Inclusion Enrollment Report format is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- ○ **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.

- ○ ***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 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.

- ○ **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 11](#).

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 application's direct costs budgeted for the entire period of performance should not exceed **$1.0M**. 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.

Partnering PI Option: 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 **$1.0M**. 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.

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 may be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.

- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project from the FY24 PCRP Data Science Award.

- Costs associated with purchase, access, and/or utilization of datasets and/or databases

Must not be requested for:

- Clinical trial costs

- Equipment

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

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*:

- **Impact**

  - *Assuming the objectives/goals of the proposed research project are realized, to what degree:*

    – The anticipated short-term outcome(s)/product(s) of the project will be used as the foundation for future research projects that will enable progress toward providing a solution to one or more of the FY24 PCRP Overarching Challenges.

    – The anticipated short-term outcome(s)/product(s) will significantly outperform current approaches, if applicable.

    – The proposed research would, in the long term, make an impact on prostate cancer patient care and ultimately contribute to the goal of eliminating death from prostate

cancer and enhancing the well-being of Service Members and their Families, Veterans, and all the patients and caregivers who are experiencing the impact of the disease.

- **Research Strategy and Feasibility**

  - How well the scientific rationale supports the research and its feasibility, as demonstrated by logical reasoning, a critical review and analysis of the published literature, and the presentation of preliminary data (if applicable) to support the research hypotheses and research approaches.

  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.

  - How well the plans for rigorous validation, benchmarking, comparison, and/or evaluation will assess the quality or utility of the proposed tool(s) and/or approach(es) (if applicable).

  - How well the application acknowledges potential problems and addresses alternative methods and approaches.

  - Whether the application provides sufficient evidence to support the availability of and access to the resources, databases, and/or samples required for the study and whether the plan for the acquisition of samples is sufficient for the proposed research project (if applicable).

  - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. 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.

- **Statistical Plan**

  - Whether the statistical plan, including sample size projections and power analysis, is adequate for the study (if applicable).

- **Personnel**

  - To what degree the research team's background is appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient clinical and/or biostatistical expertise (if applicable).

  - How appropriate the levels of effort are for successful conduct of the proposed work.

  - **Partnering PI Option:** How the partners' combined expertise will better address the research question and support why the work should be done together rather than through separate efforts.

In addition, the following **unscored criteria** will also contribute to the overall evaluation of the application:

- **Environment**

  ○ To what degree the scientific environment is appropriate for the proposed research.

  ○ How well the research requirements are supported by the availability of and access to facilities and resources (including patient populations, samples, and collaborative arrangements).

  ○ To what degree the quality and extent of institutional support are appropriate for the proposed research.

  ○ If applicable, to what degree the intellectual and material property plan is appropriate.

- **Data and Research Resources Sharing Plan**

  ○ To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider prostate cancer research community to further inform and refine the data science tools, processes, and/or methods generated and/or used in this study.

- **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**

  ○ 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 Defense Health Program and FY24 PCRP, as evidenced by the following:

  ○ Adherence to the intent of the funding opportunity

  ○ Program portfolio composition

- Programmatic relevance to FY24 PCRP Overarching Challenges

- 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 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 PCRP 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

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

Partnering PI Option: 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 and only allowed 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 [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 Institutional Animal Care and Use Committee, 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 *(only required for clinical research studies)*: 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 $10.0M 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 full applications, the following administrative actions may occur.

II.H.2.a. Rejection

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

- Pre-application was not submitted.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

- More than one application is received naming the same investigator as PI, Initiating PI, or Partnering PI. Only the first application received will be accepted; additional applications will be administratively rejected.

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 PCRP 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 PCRP Programmatic Panel members can be found at*** ***https://cdmrp.health.mil/pcrp/panels/panel24***.

- 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.

- 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 [FY24 PCRP Overarching Challenges](#).

- A clinical trial is proposed.

- The PI, Initiating PI, or Partnering PI does not meet the eligibility criteria.

- ***Partnering PI Option:*** 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	
	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"		
Transition Plan- Attachment 8, upload as "Transition.pdf"		
Inclusion of Women and Minorities- Attachment 9, upload as "Inclusion.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

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DSA	Data Science Award
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
PCRP	Prostate 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