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

Implementation Science Award

Announcement Type: Initial

Funding Opportunity Number: HT942524PCRPISA

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:** October 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 (B). 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 Implementation Science Award supports studies that are expected to bridge the gap between research, practice, and policy through establishment of a knowledge base of interventions, clinical practices/guidelines, tools, and policies that can be deployed to targeted populations at the appropriate time and point of need. For the purposes of this funding opportunity, an ***implementation science study*** accesses strategies used and develops tools to enhance the systematic uptake of evidence-based health interventions into clinical and/or community settings in order to improve patient outreach, patient outcomes, and/or the effectiveness of health care.

Impact: Research supported by the Implementation Science Award is expected to have the potential for major, near-term impact that will accelerate the widespread adoption of evidence-based practices in prostate cancer care, prevention, and survivorship. Applications are expected to identify the prostate cancer patients or at-risk individuals who would ultimately benefit from the proposed research. Applications must also include a detailed research transition plan that articulates the pathway to moving the project's findings to the next phase for widespread clinical impact after successful completion of the award. Research transition plans are encouraged to consider future strategies targeting the patient, physician/provider, community, and/or healthcare system levels as applicable.

Community Engagement: Applications are ***required*** to include members of the targeted population and/or community in the development and execution of the research project where appropriate. The research team ***must*** include one or more prostate cancer consumer advocate(s) or member(s) of the community, who will be integral throughout the planning and performance of the research project. Consumer advocates and/or community-based members should be involved in the development of the research question, project design, oversight, recruitment, and evaluation and dissemination of outcomes, as well as other significant aspects of the proposed project. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings; communication between the research team and the community should be frequent and bidirectional. The consumer advocates can be individuals who have been diagnosed with prostate cancer, a direct caregiver for someone who has been diagnosed with prostate cancer, or other representatives from the targeted community who are positioned to effect change. The consumer advocates and/or community-based members should have a high level of knowledge of current prostate cancer issues and the appropriate background in prostate cancer research and/or clinical care to contribute to the project or be otherwise positioned within the target community to effect changes in behavior based on projected outcomes. A list of implementation science resources and community or advocacy organizations is provided at the end of the Implementation Science Award Information section.

Health Equity and Disproportionately Affected Populations: Regardless of the FY24 PCRP Overarching Challenge(s) being addressed, all research projects are ***strongly encouraged*** to consider health equity (e.g., access to evidence-based care) and/or have a focus on addressing the needs of disproportionately affected populations in the application.

Research Scope: The Implementation Science Award mechanism is intended to fund studies including, but not limited to, the following:

- Small-scale clinical trials (up to phase 2) that contain clear reporting and implementation strategies to narrow the research-to-practice timeline and improve care for prostate cancer survivors, particularly within disproportionately affected populations
- Interventions that focus on behavioral or lifestyle changes at the patient, provider, community, and/or policy level
- Comparative effectiveness research establishing the benefits and harms of emerging or standard-of-care interventions and strategies to prevent, diagnose, treat, and monitor health conditions in real-world settings
- Development and evaluation of strategies to overcome barriers to health care access across the cancer care continuum
- Altering the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions, tools, policies, and guidelines.

Preliminary data to support the scientific rationale and feasibility of the research approaches are required. These preliminary data do not need to have been generated solely in prostate cancer. The inclusion of additional preliminary data to support the clinical relevance of the idea is strongly encouraged.

Investigators proposing a clinical trial are highly encouraged to consider leveraging the PCRP Prostate Cancer Clinical Trials Consortium (https://pcctc.org) to facilitate the rapid initiation and completion of the trial.

Correlative studies that are associated with ongoing clinical trials, and preclinical studies involving the use of animals do not meet the intent of the FY24 PCRP Implementation Science Award.

Partnering Principal Investigator (PI) Option: The FY24 PCRP Implementation Science Award encourages applications that include meaningful and productive collaborations between two investigators. The PIs may have expertise in similar or disparate scientific and/or clinical disciplines, but ***each PI is expected to bring distinct contributions*** to the application. 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. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PIs, 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 (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.

A Clinical Trial Option allows for studies proposing small-scale clinical trials with a focus on implementation science. 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. Applications proposing a clinical trial are expected to provide detailed plans for initiating the clinical study within the first year, including U.S. Food and Drug Administration (FDA) Investigational New Drug/Investigational Device Exemption application submission plans, within 60 days of the award.

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.

Implementation Sciences Resources: Potential applicants for this award are encouraged to seek collaborations and access to appropriate study populations through the following (or similar) resources:

- CDMRP: Search the CDMRP awards database at https://cdmrp.health.mil.
- The North Carolina – Louisiana Prostate Cancer Project (PCaP): The PCaP was supported by the PCRP to conduct prostate cancer health disparity studies and developed a large biorepository of health disparity-related epidemiological data and biospecimens that may be requested for use by the research community. Information on PCaP investigators, data, and specimens is available at https://pcap.bioinf.unc.edu.
- National Cancer Institute Center to Reduce Cancer Health Disparities: Search for health disparity research and researchers at https://crchd.cancer.gov/index.html.
- National Institute on Minority Health and Health Disparities (NIMHD), National Institutes of Health (NIH), Community-Based Participatory Research (CBPR) Initiative: Contact the NIMHD at https://www.nimhd.nih.gov/programs/extramural/community-based-participatory.html for information on current CBPR programs and scientists and communities engaged in health disparity research.
- Cancer Prevention and Control Research Network (CPCRN): Contact the CPCRN at https://cpcrn.org/ for information on community participatory research to reduce cancer in disproportionately affected populations.
- Health Resources and Services Administration, Office of Minority Health: Search for health disparity programs and funded investigators at https://www.hrsa.gov/index.html.

- NIH Research Portfolio Online Reporting Tool (NIH RePORTER): Search for NIH awards at https://projectreporter.nih.gov/reporter.cfm.

- Defense Technical Information Center (DTIC): Search for Department of Defense (DOD) and other government-funded investigators through DTIC Technical Reports at https://discover.dtic.mil/.

- National Library of Medicine, NIH, PubMed: Search for investigators publishing studies on prostate cancer health disparities at https://www.ncbi.nlm.nih.gov/pubmed.

- U.S. Department of Education: Search for institutions that may have increased access to disproportionately affected populations at https://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst.html.

- International Cancer Research Partnership: Search for investigators and studies relevant to health disparity that are supported by cancer research funders from several countries including the United States, European Union, United Kingdom, and Canada at https://www.icrpartnership.org.

- National Coalition for LGBT Health: For more information on programs focused on Lesbian, Gay, Bisexual, and Transgender (LGBT) research, policy, education, and training, search https://www.healthlgbt.org.

- National LGBT Cancer Network: To obtain more information, search https://www.cancer-network.org.

In addition, the following is a list of potential **community and/or advocacy organizations** that applicants may find helpful to satisfy the ***requirement*** for community engagement within their proposed studies: the American Indian Health Care Association, National African American Outreach Program of the Patient Advocate Foundation, National Alliance for Hispanic Health, National Medical Association, National Rural Health Association, and Prostate Health Education Network, as well as international organizations such as the African-Caribbean Cancer Consortium, African Organization for Research and Training in Cancer, Europa Uomo, European Cancer Patient Coalition, Global Prostate Cancer Alliance, Malecare, Men of African Descent and Carcinoma of the Prostate Consortium, Prostate Cancer Transatlantic Consortium, Urban League, and The Prostate Net.

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 Implementation Science Award should not exceed **$2.0M**. 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 $9.6M to fund approximately three PCRP Implementation 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-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

Independent investigators at or above the level of Assistant Professor (or equivalent) are eligible to be named as PI, Initiating PI, or Partnering PI on an application for the FY24 PCRP Implementation Science Award.

Each investigator may be named as a PI or Initiating PI on only one application for this Implementation Science Award program announcement.

There are no limitations on the number of applications for which an investigator may be named as a Partnering PI. To meet the intent of the Partnering PI Option, investigators are discouraged from being named as a Partnering PI on multiple FY24 PCRP Implementation Science Award applications unless they are clearly unique, meaningful partnerships addressing distinct research questions.

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

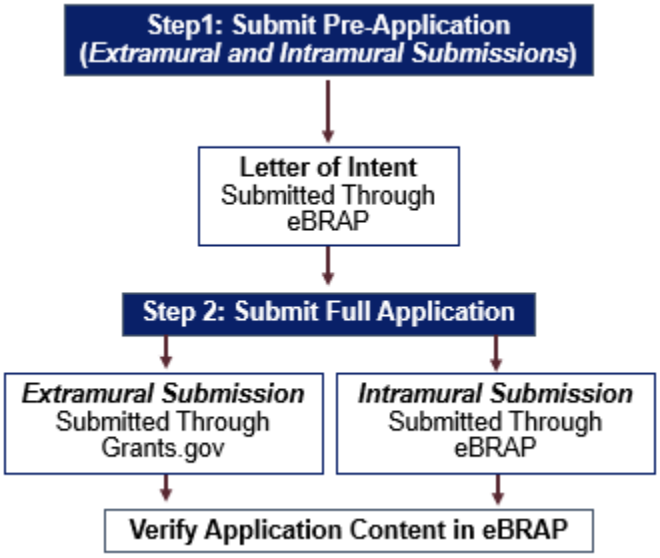
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the 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 HT942524PCRPISA 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 HT942524PCRPISA 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	Implementation Science Award
Single PI with Clinical Trial Option	Implementation Science Award with Clinical Trial Option
Partnering PI Option	Implementation Science Award – Partnering PI Option
Partnering PI Option with Clinical Trial Option	Implementation Science Award – Partnering PI Option with Clinical Trial

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. Briefly describe the planned community engagement, including the names of those individuals participating.

  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 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.

  - **Background:** Present the ideas and reasoning behind the proposed research that will be addressed. The application must provide a sound scientific rationale to support the proposed project and its feasibility as established through the demonstration of logical reasoning and a critical review and analysis of published literature; include relevant literature citations. ***Include preliminary data to support the scientific rationale and feasibility of the research approaches.*** Applications are strongly encouraged to also include preliminary data to support the clinical relevance of the idea. Any

unpublished, preliminary data provided should originate from the laboratory of the PI(s) or a member(s) of the research team.

- **Overarching Challenges:** Briefly describe how the proposed research will help address and provide a solution to one or more of the FY24 PCRP Overarching Challenges.

- **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. The specific aims should be aligned with the specific aims/tasks outlined in the Statement of Work (SOW).

- **Research Strategy and Feasibility:**

  - Describe the experimental design, methods, and analyses, including appropriate sample-size estimation and controls, in sufficient detail for analysis. Include information describing the availability of required resources, if applicable.

  - Describe, if applicable, how the study considers health equity and/or has a focus on addressing the needs of disproportionately affected populations.

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

  - 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). For clinical trials, additional details about the statistical plan should be provided under Attachment 11.

  - For human subjects or human biological samples that will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. 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. Describe the clinical expertise available to support the project, if applicable. Provide information to support the availability of and access to the appropriate resources, patient population(s), and/or samples. For clinical research, see Attachment 10 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.

  - If applicable, describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA or international regulatory agency, if required.

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.

- **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. ***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 of 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.

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

Describe the proposed research project using 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:** State the FY24 PCRP Overarching Challenge(s) the proposed research will address and ultimately provide progress toward the mission to 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. State the anticipated time to implementation.

- **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 of scientific jargon, acronyms, and abbreviations.

  - What are the likely contributions of this study to the FY24 PCRP Overarching Challenges?
  - Summarize the objectives and rationale for the proposed research.
  - What population will the research help, and how will it help them?
  - What are the potential applications, benefits, and risks of the anticipated outcomes?
  - What are the likely contributions of the proposed research project to advancing research, patient care, and/or quality of life?

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

If exercising the Partnering PI Option, 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".**

  Assume the objectives/goals of the proposed research project are realized, and then:

  - ***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) will be rapidly disseminated to advance the implementation of evidence-based care. Summarize how the anticipated outcome(s)/product(s) will enable progress towards 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 applicants are positioned to engage large or influential networks capable of taking the results of the proposed study to scale to achieve widespread public health impact. Describe how the anticipated long-term gains would make an impact on prostate cancer patient care and ultimately contribute to the goal of elimination of death and suffering from prostate cancer and enhancing 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: Community Engagement Plan: Upload as "Community.pdf".**

  Page limits for these components are noted below. 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.

- **Community Engagement (two-page limit):** Briefly describe the roles that the identified consumer advocate(s) and/or community-based member(s) from the target population will play in the proposed research project. Explain the communication plan, including how information will flow bidirectionally between the research team and the target population and/or community. Describe how the identified individual(s) and/or community-based organization(s) have a high level of knowledge of current prostate cancer issues, have appropriate background in prostate cancer research and/or clinical care, or are otherwise positioned within the target community to effect changes in behavior based on the projected outcomes of the project.

- **Consumer Advocate and Community Member Letters of Commitment (two-page limit per letter):** Provide a letter signed by each consumer advocate or community-based partner(s) confirming their role and commitment to participate on the research team. If a community-based organization will be engaged, the letter of commitment should be signed by both the organization point of contact leading the engagement along with the organization's leadership endorsing the collaboration, if different from the point of contact. The letter should include the qualifications and background of the consumer advocate(s) or community-based partner(s) and their relevance to the proposed project.

- **Attachment 9: Transition Plan (three-page limit): Upload as "Transition.pdf".** Describe/discuss the methods and strategies proposed to move the intervention to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.

  - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.

  - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A "knowledge product" is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, tools, or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

- A brief schedule and milestones for transitioning the intervention (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA).

- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- A risk analysis for cost, schedule, manufacturability, and sustainability.

- A plan to distribute the findings or intervention to the prostate cancer community.

- An assessment of the opportunities available and potential barriers that would impact the progress of commercialization, translation, and/or implementation of the study results into clinical practice and the patient community.

- **Attachment 10: Inclusion of Women and Minorities (four-page limit): Upload as "Inclusion.pdf". (*Attachment 10 is only applicable and required for applications that propose clinical research* or clinical trials.)** Briefly (one-page) 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. 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. Include a completed Inclusion Enrollment Report following this one-page description. The Public Health Service (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 11: Clinical Strategy Statement, *if applicable* (no page limit): Upload as "Clinical.pdf". If funds for a clinical trial are requested, this attachment is required.**

  - Describe the rationale for the proposed clinical trial. Provide a description of the intervention and the endpoints to be measured. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

  - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.

  - Provide detailed plans for initiating the clinical study within the first year, including FDA Investigational New Drug/Investigational Device Exemption application submission plans within 60 days of the award, if applicable. Describe how data will

be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria.

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. Include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **Attachment 12: 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 13: 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.

- ***If exercising the Partnering PI Option, 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 the Partnering 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 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 13.

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

- **Attachment 13: 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 13.

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 **4** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$2.0M**. 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 **4** 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 **$2.0M**. 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):

- Clinical trial costs (if applicable)
- Costs associated with consumer advocate and/or community member engagement.
- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY24 PCRP Implementation Science Award.

Must not be requested for:

- Costs associated with animal use
- Costs associated with correlative studies
- 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**, of which, impact is the ***highest importance***, and all others are of ***equal importance***:

- **Impact**
    - ***Assuming the objectives/goals of the proposed research project are realized, to what degree:***
        - The anticipated outcome(s)/product(s) 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) of the project can be rapidly disseminated to advance their implementation.
        - The proposed research would, in the long term, make an impact on prostate cancer patient care, and contribute towards 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.
        - The applicants are positioned to engage large or influential networks capable of taking the results of the study to scale to achieve widespread public health impact.
- **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.
    - Whether the presentation of preliminary data supports the scientific rationale and research approaches.
    - If applicable, how well the preliminary data supports the clinical relevance of the idea.
    - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
    - If applicable, how well the application considers health equity and/or has a focus on addressing the needs of disproportionately affected populations.
    - How well the application acknowledges potential problems and addresses alternative approaches.

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

- Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity is included.

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

- **Clinical Strategy (*Clinical Trial Option only*)**

  - Whether the type of clinical trial proposed is appropriate to meet the project's objectives.

  - How well the clinical trial portion of the application is designed with appropriate study variables, controls, endpoints, and data analysis plan.

  - How the application demonstrates the availability of, and access to, the appropriate study population(s), as well as the ability to accrue a sufficient number of subjects.

  - Whether the application sufficiently demonstrates the clinical trial can be initiated in the first year of the award.

  - Whether potential challenges and alternative strategies are appropriately identified.

  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA or international regulatory agency, if required.

- **Statistical Plan**

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

- **Research Transition Plan**

  - How well the application demonstrates feasible methods and strategies to transition the project's findings to the next phase of development and/or community practice after successful completion of the award.

  - Whether the application appropriately addresses available opportunities and potential barriers that could impact the progress of commercializing, translating, and/or implementing the study results into clinical practice and the patient community.

- Whether the timeline for expected post-award progress is reasonable and contains appropriate milestones and deliverables for advancing the study results toward patient impact.

- Whether the proposed research transition plan includes sufficient evidence that the PI has or can secure additional funding or whether the plan clearly describes potential options to secure the additional funding needed to bring the outcomes to the next phase of development and/or implement the study results into clinical practice and the patient community.

- Whether the collaborations and other resources described are sufficient to provide continuity of development.

- How well the plans are described for distribution of the findings or intervention to the prostate cancer community.

- **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 statistical expertise (if applicable).

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

  - If applicable, how the partnering PI's combined expertise will better address the research question.

- **Community Engagement**

  - Whether the application identifies consumer advocates and/or community-based members of the target population and how well the individuals are integrated into all aspects of the proposed research project.

  - Whether the consumer advocate(s) and/or community-based members have a high level of knowledge of current prostate cancer issues and the appropriate background in prostate cancer research and/or clinical care or are otherwise positioned within the target community to effect changes in behavior based on projected outcomes.

  - How well the communication plan is described, including how information will flow bidirectionally between the research team and target population and/or community.

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**:

- **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.

- **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.
- **Environment**
    - To what extent the scientific environment is appropriate for the proposed research project.
    - How well the research requirements are supported by the availability of and accessibility 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.
- **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

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 at the discretion of the Grants Officer.

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

Refer to full text of the latest 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.

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

II.F.4. Reporting

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

For applications proposing a clinical trial, Quarterly Technical Reports will be required.

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

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $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 or Initiating 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 PI, Initiating PI, or Partnering PI does not meet the eligibility criteria.
- The application does not address at least one of the FY24 PCRP Overarching Challenges.
- The application does not identify a required consumer advocate or other community-based member.
- The application proposes a correlative study.
- The application proposes the use of animals.
- ***Partnering PI Option:*** Failure to submit all associated (Initiating and Partnering) 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"	☐	☐
Community Engagement Plan – Attachment 8, upload as "Community.pdf"	☐	☐
Transition Plan – Attachment 9 upload as "Transition.pdf"	☐	☐
Inclusion of Women and Minorities – Attachment 10, upload as "Inclusion.pdf"	☐	☐
Clinical Strategy Statement – Attachment 11, upload as "Clinical.pdf"	☐	☐
Representations *(Extramural submissions only)* – Attachment 12, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 13, 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	☐	☐

Full Application Components	Uploaded	
	Initiating PI	Partnering PI
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
CBPR	Community-Based Participatory Research
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CPCRN	Cancer Prevention and Control Research Network
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
IRB	Institutional Review Board
ISA	Implementation Science Award
LGBT	Lesbian, Gay, Bisexual, and Transgender
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NIH RePORTER	NIH Research Portfolio Online Reporting Tool
NIMHD	National Institute on Minority Health and Health Disparities
PCaP	Prostate Cancer Project
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