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

Physician Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524PCRPPRA

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
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, September 4, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, September 4, 2024
- **Peer Review:** November 2024
- **Programmatic Review:** February 2025

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

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Prostate Cancer Research Program (PCRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the PCRP in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY23 totaled $2.26 billion. The FY24 appropriation is $110.0 million (M).

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

II.A.1. FY24 PCRP Overarching Challenges

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

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

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

  - The mental and emotional health of patients and their families/caregivers
  - Impact of quality-of-life considerations on decision-making after diagnosis and/or treatment
  - Identification of vulnerable groups of patients and their families at great risk of quality-of-life detriments
  - Implementation of factors or interventions that improve access to evidence-based care, quality-of-life outcomes, and overall health and wellness

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

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

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

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

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

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

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

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

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

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

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

II.B. Award Information

The FY24 PCRP Physician Research Award supports a mentored research experience to prepare physicians with clinical duties and/or responsibilities for productive careers in prostate cancer research. The mentored physician is considered the Principal Investigator (PI) of the application. This award emphasizes equally the quality of the proposed research project and the career development of the PI, which should prepare physicians for careers in basic, population science, translational, or clinical prostate cancer research. ***All applications for the FY24 PCRP Physician Research Award are to be written by the PI, with appropriate direction from the mentor(s).***

Key elements of this award mechanism are as follows:

- **Principal Investigator:** Physicians with clinical duties and/or responsibilities who, at the application submission deadline, are either in the last year of an accredited graduate medical education program as a resident or fellow or within 5 years of having initiated a faculty appointment (including Instructor positions) are eligible to apply. The PI must demonstrate a commitment to a career as a physician-scientist and investigator at the forefront of prostate cancer research and clinical practice; however, the PI is not required to have previous prostate cancer research experience. The award is intended to provide protection of the PI's time for prostate cancer research. Applications are strongly encouraged to demonstrate protection of at least 20% of the PI's time for prostate cancer research, which is not required to be exclusive to this award but can include effort dedicated to other prostate cancer research projects.

- **Mentor(s):** This award requires the involvement of at least one designated mentor with an established research program in prostate cancer, as evidenced by recent publications, active funding, and successful mentorship. In addition, the mentor(s) must demonstrate a commitment to advancing the PI's career in prostate cancer research.

- **Research Approach:** Proposed research ideas are ***required*** to address one or more of the FY24 PCRP Overarching Challenges. The scientific rationale and experimental methodology should demonstrate in-depth analysis of the research problem presented. The feasibility of the research design and methods should be well defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved. ***The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required.*** Any preliminary data provided should be from the PI, mentor(s), or member(s) of the collaborating team. Additionally, required resources should be identified and supported through documentation. ***Research involving human subjects is permitted under this funding opportunity but is restricted to studies without clinical trials.*** Correlative studies associated with an existing clinical trial are particularly encouraged, provided they are determined to be no greater than minimal risk by the Institutional Review Board (IRB) of record and the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight.

- **Researcher Development Plan:** An ***individualized*** researcher development plan is required and should be prepared with appropriate guidance from the mentor(s). The researcher

development plan should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise that will enable the PI to successfully complete the proposed research project and foster the PI's development as an independent prostate cancer physician-scientist. An environment appropriate to the proposed mentoring and research project must be clearly described, although any deficiencies of resources and/or mentorship at the PI's institution can be mitigated through collaboration(s) with other institutions. If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-mentor at the collaborating institution.

- **Impact:** The proposed research must address and provide a solution to one or more of the FY24 PCRP Overarching Challenges and ultimately should have the potential to make a significant impact on the program's mission of 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.

Investigators are strongly encouraged to incorporate the following components into their study design, where appropriate, in order to maximize the potential impact of the proposed research project: authentication of proposed cell lines; statistical rigor of preclinical animal experiments; and incorporation of experiments to assess clinical relevance and translatability of findings. Studies utilizing data that are derived from large patient studies that include long-term health records, biospecimen repositories, and pre-existing research and apply state-of-the-art genomic and/or proteomic analysis, bioinformatics, and/or mathematical models to such data are also encouraged. Investigators are highly encouraged to provide a letter of support indicating access to and the availability of any resources required to support the study.

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.

Clinical trials are not allowed. A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

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

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

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

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

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

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

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

The CDMRP expects to allot approximately $4.80M to fund approximately four PCRP Physician Research Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

The PI must be a physician with clinical duties and/or responsibilities who, by the application submission deadline, is either:

- In the last year of an accredited graduate medical education program, either as a resident or fellow, or
- Within 5 years of having initiated their first faculty appointment (including Instructor positions).

An investigator may be named on only one FY24 PCRP Physician Research Award application as a PI.

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

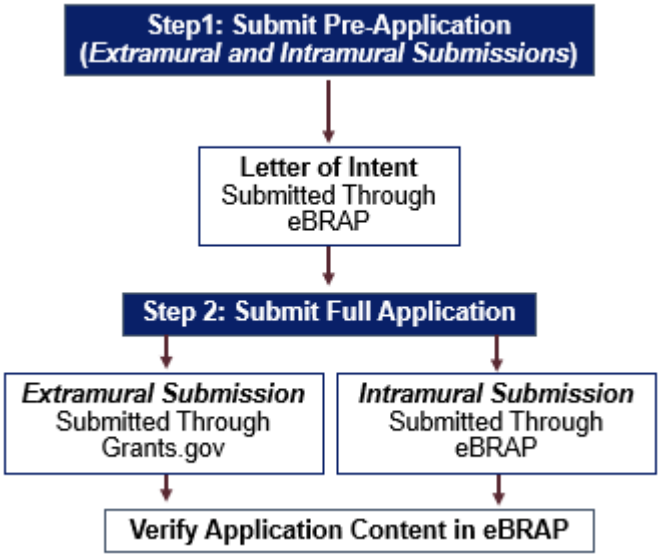
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the 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 HT942524PCRPPRA 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 HT942524PCRPPRA 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

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the PI through eBRAP.

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 the PI, Business Official(s), performing organization, and contracting organization 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.

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

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

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

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

- **List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for three individuals who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter. The three letters of recommendation must include one from the

mentor and two from the co-mentor(s) (if applicable) or other independent researchers who have had scientific knowledge and interaction with the PI.

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

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 (10-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. ***The Project Narrative must be written by the PI while also showing evidence of appropriate direction from the mentor(s).***

- **Principal Investigator**: The application should describe the PI's career goals, demonstrating a strong personal commitment to pursuing an independent career as a leader at the forefront of prostate cancer research and patient care. Describe how the proposed research project and mentoring experience will promote the PI's development toward becoming an independent prostate cancer physician-scientist. The application should discuss the PI's career plans and research plans after the completion of this award.

- **Mentor(s):** Describe each mentor or co-mentor's background and experience in prostate cancer research and mentoring as demonstrated by a record of active funding, recent publications, and successful mentorship. Explain how the mentor(s) will assist the PI throughout the period of performance in developing toward independence in prostate cancer research. Provide details on the amount and types of interactions between the mentor(s) and the PI. Describe the track record of each mentor for mentoring early career investigators in prostate cancer research.

- **Research Project**: Describe the proposed research project, including the background, hypothesis/objective, specific aims, experimental design, methods, and analyses, including the appropriate controls. The application must provide a sound scientific rationale for the proposed project and its feasibility as established through a critical review and analysis of published literature and/or logical reasoning. ***Preliminary data are not required but may be included to support the scientific rationale and feasibility of the research approaches.*** Include a statistical analysis plan for the proposed research and a power analysis to support the design and sample size (if applicable). Address potential problem areas and present alternative methods and approaches. Describe how the clinical relevance of the anticipated findings will be determined, if applicable. Explain how cell line authentication and/or statistical rigor of preclinical experiments have been incorporated into the study design, if applicable. For clinical research, see Attachment 9 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.

- **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.

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.

- **Transcripts:** Include a copy of the PI's transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of

degree), complete and include the Academic Statement (available for download on the "Full Announcement" page in Grants.gov) in place of the transcript.

- **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.

Programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project's key aspects. Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

Describe the proposed research project including the following elements:

- **Research Plan**
  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design including appropriate controls.
- **Personnel**
  - The PI's career goals and potential for a career as a leader at the forefront of prostate cancer research and patient care.
  - The strategy for acquiring necessary skills, competence, and expertise to successfully complete the proposed research project.
  - The mentor's (and co-mentor's, if applicable) background and experience in prostate cancer research and proposed contribution to the career development of the PI.
  - How the proposed research project will prepare the PI to make valuable contributions to the understanding and clinical management of prostate cancer.
- **Impact:** Summarize how the proposed research will address and provide a solution to one or more of the FY24 PCRP Overarching Challenges and ultimately provide progress toward eliminating death and suffering from prostate cancer and enhancing the well-being of Service Members and their Families, Veterans, and all the patients and caregivers who are experiencing the impact of the disease.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

The lay abstract should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

- Describe the scientific objective and rationale for the proposed research project in a manner that will be ***readily understood by readers without a background in science or medicine.***

- Describe the ultimate applicability of the research.

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

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

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

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

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

- Describe the PI's career goals in prostate cancer research and patient care.

  - How does the research plan support the PI in achieving these goals?

  - How do the mentorship and researcher development plan support the PI in achieving these goals?

- **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 Statement of Work (SOW) format and recommended strategies for assembling the SOW.

  For the Physician Research Award mechanism, refer to the ""Example: Assembling a Generic Statement of Work", for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Researcher Development Plan (one-page limit): Upload as "ResearchDev.pdf"**

  - Clearly articulate an ***individualized strategy*** that will enable the PI to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project.

  - Indicate how the ***individualized*** researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the

field of prostate cancer, and effectively prepare the PI for a career as an independent prostate cancer physician-scientist.

- Describe how the researcher development plan is supported by the environment and mentorship, including a description of ongoing prostate cancer research at the institution. Include a description of the environment of any collaborating institutions that will augment the lack of specific resources at the PI's primary institution (if applicable). If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-mentor at the collaborating institution. Include information on collaborations with other investigators, seminars, workshops, and other opportunities for professional interaction with leaders in the prostate cancer field. ***Members of the FY24 PCRP Programmatic Panel must not be involved.***

- Include mentor's (and co-mentor's, if applicable) biographical sketch.

- **Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf". Explain in detail why the proposed research project is important as follows:**

  - ***Describe the short-term impact:*** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research, including any clinically relevant results. Summarize how the anticipated outcome(s)/product(s) address(es) and will help provide a solution to one or more of the FY24 PCRP Overarching Challenges.

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

- **Attachment 8: Eligibility Statement (one-page limit): Upload as "Eligibility.pdf".** Provide a letter, signed by the PI and the Department Chair, Dean, or equivalent official, verifying that the eligibility requirements have been met by the application submission deadline. If the PI is in the last year of an accredited graduate medical education program, either as a resident or fellow, provide the date (month/year) the PI will complete their medical residency or fellowship. For PIs with a faculty appointment, provide the date (month/year) the PI began the appointment to verify that he/she is within 5 years of having initiated their first faculty appointment (including Instructor positions).

- **Attachment 9: Inclusion of Women and Minorities (four-page limit): Upload as "Inclusion.pdf". (*Attachment 9 is only applicable and required for applications that propose clinical research.*)** Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Studies utilizing

human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. The PHS Inclusion Enrollment Report format is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **Attachment 10: Transition Plan (one-page limit): Upload as "Transition.pdf**". Provide information on potential methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award (e.g., specific potential industry partners, specific funding opportunities to apply for). Provide a realistic timeline for near-term clinical investigation. In addition, provide a plan to distribute the findings or intervention to the prostate cancer community.

- **Attachment 11: 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 12: 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".

- Include mentor's (and co-mentor's, if applicable) biographical sketch

- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Biosketch_LastName.pdf".

  - Include mentor's (and co-mentor's, if applicable) previous/current/pending support

(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.

(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 12.

Additional Application Components

In addition to the complete application package, FY24 PCRP Physician Research Award applications also require the following components:

- **Three Confidential Letters of Recommendations**

  The letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files to eBRAP by 5:00 p.m. ET on the last day of the verification period. **The PI should monitor whether the letters have been received in eBRAP by viewing the status in the "Pre-Application Files" tab of the pre-application.** The PI will not be able to view the letters.

  - ***The confidential letter of recommendation from each mentor*** should include a description of the mentor's commitment to the PI's career development, mentorship

in prostate cancer research, and ability to supervise the PI's research project. Mentor letters should also address the following ***(two pages per letter recommended)***:

- The PI's potential for a highly productive career as an independent prostate cancer physician-scientist
- Details of the proposed interactions of the mentor with the PI during the PI's research project
- The mentoring environment, including ongoing prostate cancer research in the mentor's laboratory and in the organization as a whole, resources available, and how this environment will promote the development of the PI as a prostate cancer physician scientist
- The degree to which the PI participated in the project development and application preparation and the degree to which the PI will participate in the execution of the application, if funded

- ***Additional confidential letter(s) of recommendation (two pages per letter recommended)***: The remaining letter(s) should describe the PI's unique qualifications and accomplishments that highlight their potential for success as a prostate cancer researcher and clinician. Specifically, each letter should offer the writer's perspective on:
  - The PI's qualifications, characteristics, and achievements
  - The PI's potential for productivity and desire for establishing a successful and independent career in prostate cancer research and patient care
  - The relevance of the proposed research project to developing the PI's career in prostate cancer research
  - The suitability of the mentor(s) and the research environment for providing the PI with a solid foundation to support an independent career in prostate cancer research

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 **$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- 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 Physician Research Award.
- Up to 50% combined salary support for one or two support personnel (e.g., laboratory technician, research nurse, data manager)
- Clinical research costs

- Workshop costs

Must not be requested for:

- Clinical trial costs
- Equipment
- Salary support for the mentor(s) or any other senior/key personnel except the PI
- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Principal Investigator**
    - How well the PI's achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate the potential for a successful career as a prostate cancer physician-scientist.
    - To what extent the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career as a leader in prostate cancer research and patient care.
    - To what extent the letters of recommendation from the mentor(s) and others support the PI's potential for highly productive career as an independent prostate cancer researcher in addition to continuing practice as a physician.
    - Whether the proposed PI level of effort is appropriate for completion of the proposed work.
- **Mentor(s)**
    - Whether there is at least one mentor who is an established prostate cancer researcher, as evidenced by a demonstrated record of active funding and recent publications in prostate cancer research.

- How well the mentor's (and co-mentor's, if applicable) own experience in prostate cancer research and their ongoing research program and available resources support the ability to supervise the PI's research project.

- To what extent the track record(s) of the mentor(s) in previously mentoring early career investigators indicate the potential for successful mentoring of the PI in prostate cancer research.

- Whether the mentor letter(s) indicate a high level of commitment to the PI's development as an independent prostate cancer researcher.

- Whether the quality of the application suggests that the mentor(s) provided appropriate guidance in its preparation.

- **Research Project**

  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data (if included), and/or logical reasoning.

  - Whether the experimental design and the statistical analysis plan, if applicable, are appropriate for the research proposed.

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

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

  - As applicable, how well the application describes components to increase the impact of the project, including cell line authentication, statistical rigor of preclinical experiments, and/or experiments to address clinical relevance.

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

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

  - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **Research Development Plan and Environment**
    - How well the application outlines an individualized researcher development plan that will enable the PI to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project.
    - How well the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in prostate cancer research, and effectively prepare him/her for a career as an independent prostate cancer physician-scientist.
    - To what extent the scientific environment at the primary institution (and collaborating institution(s), if applicable) is appropriate for the proposed research and career development activities, including availability of professional interaction with established prostate cancer researchers.
    - To what degree the organizational commitment to adjust the PI's clinical or other responsibilities to secure additional time for research will help foster the PI's research and clinical career.
    - To what extent the research requirements are adequately supported by the availability and accessibility of facilities and resources (including collaborative arrangements and/or intellectual property plans as applicable).
- **Impact**
    - ***Assuming the objectives/goals of the proposed research project are realized, to what degree:***
        - The anticipated short-term outcome(s)/product(s) of the project will address and provide a solution to one or more of the FY24 PCRP Overarching Challenges.
        - The proposed research would, in the long term, make a major impact on prostate cancer research and/or patient care, and contribute to the goal of 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.

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**:

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

- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 PCRP, as evidenced by the following:
    - Adherence to the intent of the funding opportunity
    - Program portfolio composition
    - Programmatic relevance to the FY24 PCRP Overarching Challenges
    - Relative impact

II.E.2. Application Review and Selection Process

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

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

of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

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

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

II.F.2. PI Changes and Award Transfers

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

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 OHARO, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

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

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

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10.0M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Pre-application was not submitted.
- More than one application is received naming the same investigator as a PI. Only the first application received will be accepted; additional applications will be administratively rejected.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY24 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.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The application does not address at least one of the FY24 PCRP Overarching Challenges.

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
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"	☐
Researcher Development Plan- Attachment 6, upload as "ResearchDev.pdf"	☐
Impact Statement- Attachment 7, upload as "Impact.pdf"	
Eligibility Statement- Attachment 8, upload as "Eligibility.pdf"	
Inclusion of Women and Minorities- Attachment 9, upload as "Inclusion.pdf"	
Transition Plan- Attachment 10, upload as "Transition.pdf"	
Representations *(Extramural submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐
Additional Application Components	☐
Confidential Letters of Recommendation	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PCRP	Prostate Cancer Research Program
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRA	Physician Research Award
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