

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

Dr. Barbara Terry-Koroma¹

Health Disparity Research Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-PCRP-HDRA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), August 3, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, August 24, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, August 29, 2023
- **Peer Review:** October 2023
- **Programmatic Review:** January 2024

¹ Dr. Barbara Terry-Koroma was a devoted champion for research toward resolving health disparities in cancer incidence, morbidity, and mortality. On staff with the Congressionally Directed Medical Research Programs for 15 years, she played a major role in the Department of Defense Prostate Cancer Research Program's initiatives to address prostate cancer disparities. Dr. Terry-Koroma passed away in January 2013 and left a legacy of determination to ensure that populations disproportionately affected by disease will be the focus of needed research. For more information, see https://cdmrp.health.mil/pubs/press/2013/terrykoroma_press.

This program announcement must be read in conjunction with the General Application Instructions, version 803. 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

Applications to the Fiscal Year 2023 (FY23) Prostate Cancer Research Program (PCRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The PCRP was initiated in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY22 totaled \$2.15 billion. The FY23 appropriation is \$110 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.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY23 PCRP Overarching Challenges

The Mission of the FY23 PCRP is to fund research that will eliminate death and suffering from prostate cancer and enhance the well-being of Service members, Veterans, and all the men and their families 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 FY23 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 men and their families at great risk of quality-of-life detriments

- Translation of factors or interventions that improve quality-of-life outcomes and overall health and wellness

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

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

Treatments may address any stage in the continuum of care, including local therapies such as surgery or radiation designed to treat men 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 inequities and disparities that impact a person, their family, or their caregiver's ability to prevent, detect, manage, and survive prostate cancer.

Inequities may arise from socioeconomic status, race or ethnicity, geography, environment, lifestyle, sexual and/or gender identification, access to care (in rural or urban settings), or other factors.

Health inequities may include physical, mental, or emotional health differences, as well as social and financial differences experienced primarily in high-risk or underserved prostate cancer patients.

High-risk populations include, but are not limited to, people of African descent (including Caribbean), genetically predisposed populations, Service Members, and Veterans.

Underserved populations include, but are not limited to, men with limited access to clinical care and resources (in rural or urban settings) and sexual and/or gender minorities.

- **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. 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.A.2. FY23 PCRP Health Disparity Research Award Focus Areas

The PCRP is interested in research that addresses all different aspects that contribute to health disparity in prostate cancer. The Focus Areas outlined below broadly describe the primary areas that may contribute to disparities in prostate cancer incidence, morbidity, mortality, and survivorship:

- ***Biological contributors*** such as genetic and genomic differences, that can be associated with disparate outcomes in patient populations.
- ***Environmental factors*** that may cause endogenous changes, such as environmental exposures, dietary factors, lifestyle factors, and other external factors that may contribute to prostate cancer disparities in specific populations.
- ***Social and cultural factors*** that may influence decision-making of patients, their family, or caregiver as it relates to the screening and treatment of prostate cancer, such as the role of social/support networks, community influence, cultural or religious practices, and psychological health.
- ***Access to health care***, which may stem from geographic location, socioeconomic status, or other factors.

All applications for the FY23 PCRP Health Disparity Research Award are encouraged to address at least one of the FY23 Health Disparity Research Award Focus Areas.

II.B. Award Information

The FY23 PCRP Health Disparity Research Award supports promising research ideas that have high potential to make a significant impact in eliminating disparities in prostate cancer incidence, morbidity, mortality, and survivorship. ***Applications for this award are encouraged to be relevant to one or more of the [FY23 PCRP Health Disparity Research Award Focus Areas](#) and must explicitly state how the proposed research is related to the selected Focus Area(s).*** If the proposed project does not address one of the FY23 PCRP Health Disparity Research Award Focus Areas, the application must provide a description to justify how the project will nevertheless address another critical area believed to contribute to prostate cancer health disparities within the context of the [FY23 PCRP Overarching Challenges](#). Applications are encouraged from a spectrum of disciplines, including but not limited to, basic science, engineering, bioinformatics, population science, psycho-oncology, translational research, implementation science, and health care services.

Community Engagement: Investigators are ***highly encouraged*** to engage members of the targeted population or community in the development and implementation of their research project, where appropriate. A comprehensive, but by no means exhaustive, list of [health disparity research resources](#) and [community or advocacy organizations](#) is provided at the end of the Health Disparity Research Award Information section. Applications that involve and utilize population- or community-based organizations to support their research project should demonstrate the level of involvement in [letters of support](#) for the application.

Impact: Research supported by the FY23 PCRP Health Disparity Research Award is expected to have the potential to make a significant impact in addressing prostate cancer health disparities within the context of the [FY23 PCRP Overarching Challenges](#). Research with a high degree of innovation is anticipated to have a higher potential for significant impact. The impact of the proposed research may include an improved understanding of factors contributing to health disparities or provide advancements that will reduce disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship. Applications must also include a detailed [research transition plan](#) that articulates the pathway to moving the project's findings to the next phase of development after successful completion of the award and continue advancing the research toward making a clinical impact, even if clinical impact is not an immediate outcome. Research transition plans are encouraged to consider not just the pathway to developing tangible products (e.g., drugs or diagnostic assays) into clinical testing, but also the implementation of research findings and other evidence-based practices into clinical practice and patient communities.

Research Scope: Proposed projects may include basic, translational, or clinical research, including clinical trials. A clinical trial is 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. Only small-scale, early (i.e., up to and including phase 2 or equivalent) clinical trials are allowed. Investigators proposing a clinical trial are highly encouraged to consider leveraging the PCRP Prostate Cancer Clinical Trials Consortium (<http://pcctc.org/>) to facilitate the rapid initiation and completion of the trial. ***Inclusion of preliminary data is encouraged but not required.*** Any preliminary, unpublished data provided should be from the Principal Investigator (PI) or a member(s) of the research team. The PCRP strongly encourages applications proposing implementation science research that will improve the understanding and translation of research findings and other evidence-based practices into clinical practice and patient communities with respect to addressing prostate cancer health disparities.

Projects proposing to investigate the biological basis of health disparity within one or more populations are encouraged to carefully consider the proposed research methods. The application should especially consider the impact of stratifying populations by either (1) genetic and/or genomic classification of the population(s) or (2) self-reported race, and ensure that the application justifies the selected approach. Applications must include a robust statistical plan with complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

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. Investigators are highly encouraged to provide a letter of support indicating access to and the availability of any resources required to support the study.

New Investigator Category: This award encourages research ideas from investigators in the early stages of their careers. The New Investigator category is designed to allow applicant organizations to name PIs who are ***early in their faculty appointments or in the process of developing independent research careers.*** Applications submitted to the New Investigator

category will be assessed using different review criteria for personnel (refer to [Section II.E.1.a, Peer Review](#)), and are **required** to include a collaborator (or collaborators) who has (have) experience in prostate cancer health disparity research, as demonstrated by a record of funding and publications. The application must describe the potential of the collaboration(s) to be successful and how the collaboration(s) will augment the PI's expertise to better address the research question. In addition, applicants are strongly encouraged to provide a letter of collaboration from the collaborator(s) describing the collaborator(s) involvement in the proposed work. All applicants for the New Investigator category must meet specific eligibility criteria described in [Section II.C, Eligibility Information](#).

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (<https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research>) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY23 PCRFP priorities.

Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the partners bring to the research effort, ultimately advancing cancer research that is of significance to the Warfighter, military families, and the American public.

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DOD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY23 PCRFP Health Disparity Research Award should not exceed **\$900,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$11.52M to fund approximately eight FY23 Health Disparity Research Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific 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 FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is **not** required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of **all required and complete** documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page https://mrhc.health.mil/index.cfm/collaborate/research_protections/hrpo for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research **must** rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical research encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. **For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.** Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research 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 study 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 tissues that cannot be linked to a living individual.

Note: Studies that meet the requirements for exemption under [§46.104\(d\)\(4\) of the Common Rule](#) are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

A clinical trial is defined 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.

Use of DOD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA 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. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

Research Involving Animals: All research funded by the FY23 PCRP Health Disparity Research Award involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. **Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.** Refer to the General Application Instructions, Appendix 1, for additional information.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of 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 (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.

Health Disparity Research 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 <http://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 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 <http://www.healthlgbt.org>.
- National LGBT Cancer Network: To obtain more information, search <https://www.cancer-network.org>.

In addition, applicants are encouraged to interact with **community or advocacy organizations**, as applicable to their proposed studies, such as 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.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: An application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Each investigator may be named on only one FY23 Health Disparity Research Award application as a PI.

Although a PI may be eligible for both the Established Investigator and New Investigator categories, only one category may be chosen; the choice of application category is at the applicant's discretion.

- **Established Investigator**

Independent investigators at all levels are eligible.

- **New Investigator**

By the application submission deadline, the PI must:

- Have the freedom to pursue independent research goals without formal mentorship.

- Not previously have received a PCRP Health Disparity Research Award and/or Idea Development Award.
- Be an independent, early-career investigator within 10 years after completion of their terminal degree (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.
- New Investigators working within a laboratory team are eligible to apply for this award provided they can demonstrate that they have the freedom to pursue independent research goals without formal mentorship. Graduate students and junior postdoctoral fellows with less than 3 years postdoctoral training by the application submission deadline are not eligible for this award.

Investigators named as PI under the New Investigator category must confirm eligibility in [Attachment 8](#) (Eligibility Statement) and independence, if applicable in [Attachment 9](#) (Statement of Independence).

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or 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).

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. Refer to the General Application Instructions Appendix 2, Section E.

II.D.1. eBRAP and Grants.gov

The **electronic Biomedical Research Application Portal (eBRAP)** (<https://ebrap.org>) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (<https://grants.gov>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

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

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

The application title, eBRAP log number, 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. Step 1: Pre-Application Submission Content

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

When starting the pre-application, PIs should ensure that they have selected the appropriated application category:

- Health Disparity Research Award – ***New Investigator***; or
- Health Disparity Research Award – ***New Investigator with Clinical Trial Option***; or
- Health Disparity Research Award – ***Established Investigator***; or
- Health Disparity Research Award – ***Established Investigator with Clinical Trial Option***

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that applicants identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application. Include the name of any community partner(s), if applicable, and their affiliated community or advocacy organization.

[FY23 PCRP Programmatic Panel members](#) should not be involved in any pre-application or 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.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the topic area 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 sessions. An invitation to submit is *not* required.

- **Tab 6 – Submit Pre-Application**

This tab must be completed for the pre-application to be accepted and processed.

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

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the **same version** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for HT9425-23-PCRP-HDRA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for HT9425-23-PCRP-HDRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General	Tab 1 – Summary: Provide a summary of the application information.

Extramural Submissions	Intramural DOD Submissions
Application Instructions, Section III.A.1, for detailed information.	Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form 	<p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/

Extramural Submissions	Intramural DOD Submissions
<p>until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>.</p>	<p>Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>. Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
Further Information	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components

- Extramural Applications Only**

SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- Extramural and Intramural Applications**

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 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space,

and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

- **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 to expand 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; explain how the proposed project addresses one or more of the [FY23 PCRP Health Disparity Research Award Focus Areas](#), or another critical area believed to contribute to prostate cancer health disparities within the context of the [FY23 PCRP Overarching Challenges](#). Cite the relevant literature. 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. Describe previous experience most pertinent to this application. While not required, include any preliminary data to support the scientific rationale.
- **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Research Strategy and Feasibility:**
 - Describe the experimental design, methods, and analyses, including appropriate controls and endpoints to be tested (if applicable), in sufficient detail for evaluation. Clearly state how the proposed models address the identified area of prostate cancer health disparity.
 - Explain how this research strategy will meet the research goals and milestones. Address potential pitfalls and problem areas and present alternative methods and approaches.
 - Clearly identify the source of any proposed cell lines and whether they were recently authenticated and/or tested for mycoplasma contamination, if applicable.
 - Describe the availability of and access to the necessary resources, including human subjects or human anatomical samples; include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the rationale for

identifying and stratifying the proposed population(s) (genetic and/or genomic vs. self-reported classification). Address any potential ethical concerns. Outline how approvals from local IRBs will be obtained and how the informed consent process will be initiated, as applicable.

- Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects, if applicable.
 - Describe the statistical analysis plan, including a power analysis that reflects sample size projections and will address the hypothesis and/or the objectives of the project. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE 2.0 (Animal Research Reporting *In Vivo* Experiments) guidelines (<https://arriveguidelines.org/arrive-guidelines>).
 - If the study does not include a clinical trial, describe how the clinical relevance of the anticipated findings will be determined, and whether the results will be validated in the appropriate patient cohorts, if applicable.
- **Clinical Trial (*only required for applications submitted under the Clinical Trial Option*): Only small-scale (i.e., up to and including phase 2 or equivalent) clinical trials are allowed.** Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and how it will meet the project’s objectives. Outline the proposed methodology in sufficient detail to show a clear course of action. Include a description of the following clinical trial components:
- Describe the rationale for the trial and summarize the previous work that led to the development of the proposed clinical trial.
 - Provide detailed plans for initiating the clinical trial ***within the first year of the award*** and for conducting the clinical trial during the course of this award. Describe potential challenges and alternative strategies where appropriate.
 - Identify the intervention to be tested and describe the projected outcomes. As appropriate, outline a plan for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other U.S. Food and Drug Administration [FDA] approvals).
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the inclusion and exclusion criteria, the availability of and access to the appropriate patient population(s), and the ability to accrue a sufficient number of subjects for the clinical trial.

- Describe the strategy for the inclusion of women and minorities in the clinical trial 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, if applicable.
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
 - Describe the statistical model and data analysis plan with respect to the study objectives. Specify the number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
 - Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, statistician) possesses the appropriate expertise in conducting clinical trials.
- **Research Team:** Discuss the qualifications of the research team, including any prostate cancer- and health disparity-related expertise relevant to the proposed study. Outline each individual’s specific contributions to the project, including how the appropriate expertise is incorporated to address the research question and enable the success of the proposed project. If prospective clinical studies are included, the PI or research team must demonstrate appropriate expertise in conducting clinical studies.
- ***New Investigator Category Only:*** Name the required collaborator(s) and describe how the collaborator(s) involvement and prior experience in health disparity research will appropriately complement the PI’s ability to perform the proposed work.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. 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 that includes the full citation (i.e.,

author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- **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 Support from Population- or Community-Based Organizations (if applicable):** In cases where the PI is affiliated with a designated population- or community-based organization (see [Health Disparity Research Resources](#) and additional [community/advocacy organizations](#) in [Section II.B, Award Information](#)), inclusion of a letter of support from each organization is encouraged. Such letter(s) of support should explain the nature of the PI’s relationship to the organization, the involvement of the PI with the affected population or community, the importance of the project within the affected population or community, the degree of involvement of community/organization members in the proposed research project, any long-term application of the project to the affected population or community, and the PI’s commitment to the affected population or community and health disparity.
- **Letters of Collaboration:** Provide a signed letter from each collaborating individual or organization demonstrating that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
 - **New Investigators (if applicable):** Investigators applying for the New Investigator category are strongly encouraged to provide a signed letter from each collaborating individual or organization that describes how they will support the

project, to include unique expertise and/or availability of and access to research resources.

- **Letters of Support (if applicable):** Provide a signed letter from any organizations providing resources or biospecimens for the proposed study that will demonstrate that the PI has the support and access to resources necessary for the proposed work.
- **Intellectual Property:** Information can be found in the 2 CFR 200.315, “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Data Management Plan (two-page limit):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instruction 3200.12](#).
 - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.
 - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.
- **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 from 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. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution 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.
- **Inclusion of Women and Minorities (if applicable):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The 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 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. **Do not include proprietary or confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

Describe the proposed research project, including the following elements:

- **Background:** Present the ideas and reasoning behind the proposed project. Explain the relevance of the proposed project to one or more of the [FY23 PCRP Health Disparity Research Award Focus Areas](#) or justify how the project will nevertheless address a critical disparity-related need within the context of the [FY23 PCRP Overarching Challenges](#).
 - **Hypothesis/Objective:** 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.
 - **Impact:** Describe the potential near-term and long-term impact of the proposed project on eliminating disparities in prostate cancer incidence, morbidity, mortality, and survivorship in the targeted population(s) within the context of the [FY23 PCRP Overarching Challenges](#).
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information. Do not duplicate the technical abstract.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay abstract should be written using the outline below. 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 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.
 - How is this study relevant to one or more of the [FY23 PCRP Health Disparity Research Award Focus Areas](#), or what other critical disparity-related need within the context of the [FY23 PCRP Overarching Challenges](#) will this study address?
 - What are the likely contributions of this study toward the goal of eliminating disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship within the context of the [FY23 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.
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested Statement of Work (SOW) format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the FY23 PCRP Health Disparities Research Award, refer to either the “*Suggested SOW Strategy Clinical Research*” or “*Suggested SOW Strategy Generic Research*”, whichever format is most appropriate for the proposed effort, and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** Summarize how the proposed project addresses one or more of the [FY23 PCRP Health Disparity Research Award Focus Areas](#) or critical disparity-related need (within the context of the [FY23 PCRP Overarching Challenges](#).
 - ***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 (short-term impact). Explain how the anticipated short-term results will help improve the understanding of factors contributing to health

disparities, and/or provide advancements that will reduce disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship.

- ***Describe the long-term impact:*** Explain the anticipated long-term gains from the proposed research, including how the new understanding will lead to the significant reduction or elimination of prostate cancer health disparities in the targeted population(s).
- o **Attachment 7: Research Transition Plan (two-page limit): Upload as “Transition.pdf”.** Provide information on potential methods and strategies to feasibly transition the project’s findings to the next phase of development and/or community practice after successful completion of the award. Research transition plans should include further development of tangible products (e.g., drugs or diagnostic assays) into clinical testing, as well as the implementation of research findings and other evidence-based practices into clinical practice and patient communities. The following components should be included in the transition plan, as appropriate for the anticipated project results.
 - A description of the scientific or technical requirements needed to advance the research findings.
 - A plan to distribute the findings or intervention to the targeted disparity population(s), as well as the wider 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.
 - Details of the funding strategy that will be used to bring the outcomes to the next phase of development and/or implementation of the study results into clinical practice and the patient community. Provide sufficient evidence that the PI has or can secure additional funding and describe potential options to secure the additional funding needed to bring the outcomes to the next phase of development (e.g., specific potential industry partners; specific funding opportunities to apply for; community resources).
 - A description of collaborations and other resources that will be used to provide continuity of development.
 - For knowledge products,² include proposed development or modification of clinical practice guidelines and recommendations, provider training materials,

² 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, or 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.

patient brochures, and other clinical support tools, scientific journal publications, models, and applications.

- A timeline with defined milestones and deliverables describing the expected post-award progress of the results toward patient impact.
- **Attachment 8: Eligibility Statement (one-page limit): Upload as “Eligibility.pdf”** (*Attachment 8 is only applicable and required for applications submitted under the New Investigator category*). *The Eligibility Statement will only be used for administrative purposes to confirm eligibility and will not be forwarded for peer or programmatic review.* Provide a statement, signed by the PI and Department Chair, Dean, or equivalent official, verifying that the PI will have met the eligibility requirements by the application submission deadline. The statement should clearly state that the PI:
 - Has the freedom to pursue independent research goals without formal mentorship;
 - Has not previously received a PCRP Idea Development Award and/or Health Disparity Research Award; and
 - Is an independent, early-career investigator within 10 years after completion of their terminal degree by the time of the application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. Provide an explanation for any lapses in research time or appointments.
- **Attachment 9: Statement of Independence (one-page limit): Upload as “Independence.pdf”** (*required only for investigators not yet in an independent faculty position*). For investigators not yet in an independent faculty position, provide a statement, signed by the PI and the PI’s mentor, that supports the PI’s ability to perform as an independent researcher. The Statement of Independence must include the following components:
 - PI’s name, organization, and application title
 - Beginning and ending dates (month/year) of postdoctoral training
 - Date (month/year) the PI began or will begin independent research in the proposed setting
 - Other information that attests to the PI’s independence (e.g., grants/fellowships obtained; awards/appointments earned by the PI)
- **Attachment 10: Representations, if applicable (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 5, Section B, Representations.

- **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf”.
 - Include biographical sketch for the collaborator, if applying under the *New Investigator* category
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
 - Include previous/current/pending support for the collaborator(s), if applying under the *New Investigator* category.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as “BudgetJustification.pdf”. The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 11](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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/SAM/>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. *As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.* Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. 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.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***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 application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.

Intramural DOD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be

modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

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

The application's direct costs budgeted for the entire period of performance should not exceed **\$900,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.

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

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

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

- Support of multidisciplinary collaborations, including travel.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY23 PCRP Health Disparity Research Award.

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.***

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, 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 evaluated according to the following **scored criteria**, which are listed *in decreasing order of importance*:

- **Impact**
 - How well the proposed research addresses one or more of the [FY23 PCRP Health Disparity Research Award Focus Areas](#) or another critical area believed to contribute to prostate cancer health disparities (within the context of the [FY23 PCRP Overarching Challenges](#))
 - *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 help improve the understanding of factors contributing to health disparities, and/or provide advancements that will reduce disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship
 - The long-term gains from the proposed research will lead to a significant reduction or elimination of prostate cancer health disparities in the targeted population(s)
- **Research Strategy and Feasibility**
 - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the published literature, preliminary data (if applicable), and/or logical reasoning
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses, including statistical analyses, are developed
 - Whether the proposed models are appropriate to address the identified area of prostate cancer health disparity
 - How well the application acknowledges potential pitfalls and problem areas and addresses alternative methods and approaches
 - Whether the application provides sufficient rationale for identifying and stratifying the proposed populations, and has provided sufficient evidence to support the availability of and access to the necessary resources, human subjects, and/or human anatomical samples required for the study

- Whether the strategy for the inclusion of women and minorities and distribution of proposed enrolment are appropriate for the proposed research (if applicable)
- Whether the application includes an appropriate statistical plan with power analysis (if applicable)
- If applicable, how well the application describes components to increase the impact of the project, including cell line authentication, proper design of animal studies to achieve reproducible and rigorous results in accordance with the ARRIVE 2.0 guidelines (<https://arriveguidelines.org/arrive-guidelines>) and/or experiments to address clinical relevance
- **Clinical Strategy (*Clinical Trial Option only*)**
 - Whether the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives
 - Whether the clinical trial is designed with appropriate study variables, controls, and endpoints
 - How the application demonstrates the availability of, and access to, the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects
 - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research (if applicable)
 - Whether the plan for applying for and obtaining IND/IDE status (or other FDA approvals) is appropriate, if applicable
 - 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
- **Personnel**
 - To what extent the research team's background and prostate cancer- and health disparity-related expertise are appropriate with respect to its ability to perform the proposed work
 - To what extent the levels of effort are appropriate for successful conduct of the proposed work
 - How well the letters of support describe engagement of members of the targeted population or community in the development and/or implementation of the proposed research project, if applicable

New Investigator category only:

- How well the PI's record of accomplishment demonstrates their potential for contributing to the prostate cancer health disparity research field and completing the proposed work
- How well the proposed contributions of the required collaborator(s) included on the research team will appropriately complement the PI's ability to perform the proposed work
- **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 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 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 targeted disparity population(s), as well as the wider prostate cancer community

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

- **Data Resource Sharing**
 - 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**
 - If applicable, to what degree the intellectual and material property plan is appropriate
 - To what extent the scientific environment is appropriate for the proposed research
 - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements)
 - To what extent the quality and extent of organizational support are 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 mission of the Defense Health Program and FY23 PCRCP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition with consideration of New and Established Investigators
 - Programmatic relevance to [FY23 PCRCP 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>. An information paper describing the funding

recommendations and review process for the award mechanisms for the PCRCP will be provided to the PI and posted on the CDMRP website.

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 panel. Violations of confidentiality can result in the dissolving 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 another 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 the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

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.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY23 funds are anticipated to be made no later than September 30, 2024. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, other non-profit or for-profit 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. Refer to the General Application Instructions, Section III.A.5.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds. 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.**

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. 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 and 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 2, Section B, for general information on organization or PI changes.

II.F.2. 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 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#) and the [USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions](#) for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

The Award Terms and Conditions will specify if 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 and clinical trials*): Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to FAPIIS 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 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the eBRAP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by 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 803a. The program announcement numeric version code will match the General Application Instructions version code 803.

II.H.2. Administrative Actions

After receipt of applications, the following administrative actions may occur:

II.H.2.a. Rejection

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

- An FY23 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. *A list of the FY23 PCRP Programmatic Panel members can be found at <https://cdmrp.health.mil/pcrp/panels/panel23>.*

- 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY23, 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>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- 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 may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Application includes research data that are classified and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security will be considered for application withdrawal.
- The application does not address at least one of the [FY23 PCRP Overarching Challenges](#).
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.

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. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance (extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only)	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Research Transition Plan: Upload as Attachment 7 with file name "Transition.pdf"	
	<i>(New Investigator category only)</i> Eligibility Statement: Upload as Attachment 8 with file name "Eligibility.pdf" if applicable	
	<i>(New Investigator category only)</i> Statement of Independence: Upload as Attachment 9 with file name "Independence.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf"	
Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	

Application Components	Action	Completed
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget (extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget (intramural submissions only)	Suggested DOD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research Reporting <i>In Vivo</i> Experiments
CBPR	Community-Based Participatory Research
CDMRP	Congressionally Directed Medical Research Programs
CPCRN	Cancer Prevention and Control Research Network
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LGBT	Lesbian, Gay, Bisexual, and Transgender
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NIMHD	National Institute on Minority Health and Health Disparities
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID, Inc.
PCaP	North Carolina – Louisiana Prostate Cancer Project
PCRP	Prostate Cancer Research Program
PDF	Portable Document Format

PHS	Public Health Service
PI	Principal Investigator
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
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