

# **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**

**Idea Development Award**

**Announcement Type: Initial**

**Funding Opportunity Number: HT9425-23-PCRP-IDA**

**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), June 29, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, July 20, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, July 25, 2023
- **Peer Review:** September 2023
- **Programmatic Review:** November 2023

*This program announcement must be read in conjunction with the General Application Instructions, version 802. 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 (B). 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.B. Award Information

The FY23 PCRP Idea Development Award is intended to support new ideas that represent innovative approaches to prostate cancer research and have the potential to make an important contribution to the PCRP Mission. The key components of this award mechanism are:

- **Innovation:** Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, leverage unique study populations, or exhibit other highly creative qualities. Research that is an incremental advance upon published data is not considered innovative. Projects involving multidisciplinary and/or data science approaches are especially encouraged.
- **Impact:** Applications are required to address and provide a solution to one or more of the [FY23 PCRP Overarching Challenges](#). The potential impact of the research, both short-term and long-term, in addressing the FY23 PCRP Overarching Challenge(s) should be clearly described. High-impact research will, if successful, significantly advance prostate cancer research and/or patient care.
- **Preliminary Data:** Due to this award's emphasis on innovation, the presentation of preliminary data relevant to prostate cancer and the proposed project is encouraged, but *not required*. Any unpublished, preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or a member(s) of the research team. Regardless of whether preliminary data are included, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

To maximize the potential for impact, investigators are strongly encouraged to incorporate the following components into their study design where appropriate: authentication of proposed cell lines; statistical rigor of preclinical animal experiments and epidemiological studies; incorporation of experiments to assess clinical relevance and translatability of findings; and validation in patient cohorts. Investigators considering use of resources are highly encouraged to provide a letter of support indicating access to and the availability of the desired resources to support the study.

***New Investigator category:*** The FY23 PCRP Idea Development Award mechanism encourages research ideas from investigators in the early stages of their careers. The New Investigator category of this award mechanism 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 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](#).

Multidisciplinary projects are encouraged, and multi-institutional projects are allowed. Each proposed study must include a clearly stated plan for interactions among all team members and organizations involved. The plan must include communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

***Research involving human subjects is permitted under this funding opportunity; however, clinical trials are not allowed.*** Correlative studies associated with an existing clinical trial are particularly encouraged. Any studies requiring the prospective recruitment or use of human subjects through clinical research must be determined to be no greater than minimal risk by the Institutional Review Board (IRB) of record and the USAMRDC, Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO).

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.

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 PCRP 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 anticipated direct costs budgeted for the entire period of performance for an FY23 PCRP 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 \$36M to fund approximately 25 FY23 PCRPA Idea Development 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 OHARO, OHRO, prior to research implementation. This administrative review requirement is in addition to the local 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](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 the CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

***Clinical trials are not allowed. 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 Idea Development 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 Landis SC 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](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>.



## **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 PCRP Idea Development 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 PI's discretion.***

- ***New Investigator***

By the application submission deadline date, the PI must:

- Have the freedom to pursue independent research goals without formal mentorship.
- Have not previously received a PCRP Idea Development Award and/or Health Disparity Research 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).

- ***Established Investigator***

- Independent investigators at all levels are eligible

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). This includes submission of similar or identical aims as part of a larger, expanded proposal within the same program.***

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, 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](mailto: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](mailto: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](mailto:help@eBRAP.org) or 301-682-5507.

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.

[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](mailto: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. 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  |
|--|---|
| <b>Application Package Location</b>  |   |
| Download application package components for HT9425-23-PCRP-IDA from Grants.gov ( <a href="https://grants.gov">https://grants.gov</a> ) 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-IDA from eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).  |
| <b>Full Application Package Components</b>   |   |
| <b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.   | <p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>   |
| <p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> </ul>          | <p><b>Tab 3 – Full Application Files:</b> 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"> <li>• <a href="#">Attachments</a></li> </ul> |

| Extramural Submissions  | Intramural DOD Submissions  |
|---|---|
| <ul style="list-style-type: none"> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> </ul>   | <ul style="list-style-type: none"> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b><br/>Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>   |
| Application Package Submission  |   |
| <p><b>Create a Grants.gov Workspace.</b><br/>Add participants (investigators and Business Official) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b><br/>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 <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><i>Note:</i> 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. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p> | <p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> 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. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p> |
| <a href="#">Application Verification Period</a>   |   |
| <p>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 may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b></p>  | <p>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 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 <b><i>with the exception of the Project Narrative and</i></b></p>   |

| Extramural Submissions  | Intramural DOD Submissions   |
|---|--|
|   | <b>Research &amp; Related Budget Form.</b> 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. |
| Further Information   |  |
| <p><b>Tracking a Grants.gov Workspace Package.</b><br/>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> | Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.   |

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 and the [FY23 PCRPP Overarching Challenge\(s\)](#) that will be addressed. The application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature; include relevant literature citations. Describe previous experience most pertinent to this application. While not required, include any preliminary data to support the scientific rationale.
- **Hypothesis or 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, in sufficient detail for scientific evaluation that will include an assessment of overall project feasibility.
  - Address potential problem areas and present alternative methods and approaches.
  - Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, including the statistical expertise available to support the analysis, if applicable. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines 2.0 (<https://arriveguidelines.org/arrive-guidelines>) to achieve reproducible and rigorous results.
  - If human subjects or human biological samples will be used, provide evidence supporting the availability of and access to any populations/samples required for the study, including any clinical expertise. Include a detailed plan for the recruitment of subjects or the acquisition of samples, and for acquiring any additional research resources necessary for conducting the proposed research project. ***This award does not support clinical trials.*** For [clinical research](#), see [Attachment 10](#) for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.
  - Clearly identify the source of any proposed cell lines and whether they were recently authenticated and/or tested for mycoplasma contamination, if applicable.

- 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.
- **Required Collaborator (*for New Investigator category only*):** Name the required collaborator; describe their prostate cancer-related expertise and how the contribution of the collaborator will support the PI and project.
- **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 Collaboration (if applicable):** 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.
  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **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 (2-page limit):** Describe the data management plan in accordance with Section 3.c. Enclosure 3, [DoD Instructions 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.
- **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.
- **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:** Summarize the potential near-term and long-term impact of the proposed research. Include how the anticipated outcomes will provide a foundation for future research projects that will enable progress towards a solution to one or more of the [FY23 PCRP Overarching Challenges](#) and ultimately make a major impact toward eliminating death and suffering from prostate cancer and enhancing the well-being of Service members, Veterans, and all the men and their families who are experiencing the impact of the disease.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. 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. ***Do not duplicate the technical abstract.*** Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

- Clearly describe, in a manner ***readily understood by readers without a background in science or medicine***, the rationale, objective, and aims of the application.
- Describe the ultimate applicability of the research.
  - What are the likely contributions of this study to 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 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 Idea Development Award mechanism, refer to the “***Suggested SOW Strategy Generic Research***” document for guidance on preparing the SOW 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”.** Explain in detail why the proposed research project is important, as follows:
  - ***Describe the short-term impact:*** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research, including any clinically relevant results. Summarize how the anticipated outcome(s)/product(s) will provide a foundation for future research projects that will enable progress towards a solution to one or more of the [FY23 PCRP Overarching Challenges](#).
  - ***Describe the long-term impact:*** Explain the anticipated long-term gains from the proposed research, including the anticipated advantages that the new understanding may contribute to the goal of elimination of death and suffering from prostate cancer

and enhancing the well-being of Service members, Veterans, and all the men and their families who are experiencing the impact of the disease.

- **Attachment 7: Innovation Statement (one-page limit): Upload as “Innovation.pdf”.** Describe how the proposed work is innovative by proposing new paradigms, challenging existing paradigms, or otherwise being highly creative. Describe how the proposed research represents more than an incremental advancement on published data.

The following examples of ways in which the proposed work may be innovative, although not all-inclusive, are intended to help the PI frame the innovative features of their application:

- **Study concept:** Investigation of a novel idea and/or research questions.
  - **Research methods or technologies:** Use of novel research methods; new technologies, including technology development; or unique study populations to address a research question.
  - **Existing methods or technologies:** Application or adaptation of existing methods or technologies for novel research or clinical purposes or for research or clinical purposes that differ fundamentally from those originally intended.
- **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: Inclusion of Women and Minorities (four-page limit): Upload as “Inclusion.pdf”.** (*Attachment 10 is only applicable and required for applications that propose clinical research.*) Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. The Public Health Service (PHS) Inclusion Enrollment Report format is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
  - **Attachment 11: 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 12: 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 National Institutes of Health 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 required 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 required collaborator, 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 12](#). (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. No budget will be approved by the government exceeding **\$900,000** direct costs or using an indirect cost rate exceeding 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 must be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY23 PCRP Idea Development Award.

Must not be requested for:

- Clinical trial costs

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**, of which Innovation and Impact are equally the most important, with the remaining criteria listed in decreasing order of importance:

- **Innovation**
  - To what degree the research proposes new paradigms, challenges existing paradigms, or is otherwise highly creative
  - To what degree the proposed research represents more than an incremental advance upon published data

- **Impact**

- *Assuming the objectives/goals of the proposed research project are realized, to what degree:*
  - The anticipated short-term outcome(s)/product(s) of the project will be used as the foundation for future research projects that will enable progress towards providing a solution to one or more of the [FY23 PCRP Overarching Challenges](#)
  - The proposed research would, in the long term, contribute towards eliminating death and suffering from prostate cancer and enhancing the well-being of Service members, Veterans, and all the men and their families who are experiencing the impact of the disease

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of published literature, the presentation of preliminary data (if applicable), and logical reasoning
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed
- How well the application acknowledges potential problems and addresses alternative approaches
- Whether the application includes an appropriate statistical plan with power analysis (if applicable)
- Whether the application provides sufficient evidence to support the availability of and access to the populations/samples required for the study and whether the plan for acquiring the necessary research resources is sufficient for the proposed research project (if applicable)
- As 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, experiments to address clinical relevance, and/or validation in the appropriate patient cohorts
- For clinical research, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research (if applicable)

- **Personnel**

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

- Whether the levels of effort are appropriate for successful conduct of the proposed work
- New Investigator category only:
  - How well the PI’s record of accomplishment demonstrates their potential for contributing to the prostate cancer research field and completing the proposed work
  - How well the background, prostate cancer-related expertise, and proposed contribution of the required collaborator (or collaborators) will support the PI and the proposed project

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

- **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**

- How well the research requirements are supported by availability of and access to facilities and resources (including collaborative arrangements)

- **Data and Resources Sharing Plan**

- To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider prostate cancer research community

- **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 PCRP, 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 the [FY23 PCRP Overarching Challenges](#)
- Relative impact and innovation

## **II.E.2. Application Review and Selection Process**

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

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 whether additional and/or more frequent reporting is required.



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

PHS Inclusion Enrollment Reporting Requirement (*only required for clinical research studies 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](mailto: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](mailto: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 802a. The program announcement numeric version code will match the General Application Instructions version code 802.

### **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.
- Applications that include research data that are classified and/or propose research of which the anticipated outcomes may be classified or deemed sensitive to national security will be considered for application withdrawal.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not address at least one of the [FY23 PCRP Overarching Challenges](#).
- A clinical trial is proposed.
- 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 ( <b>extramural submissions only</b> )                               | Complete form as instructed  |           |
| Summary (Tab 1) and Application Contacts (Tab 2) ( <b>intramural submissions only</b> )  | 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"   |           |
|  | Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf"   |           |
|  | <i>(New Investigator category only)</i> Eligibility Statement: Upload as Attachment 8 with file name "Eligibility.pdf" if applicable |           |
|  | Statement of Independence: Upload as Attachment 9 with file name "Independence.pdf" if applicable                                    |           |
|  | Inclusion of Women and Minorities: Upload as Attachment 10 with file name "Inclusion.pdf" if applicable                              |           |
|  | Representations, applicable (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf"                 |           |
| Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable |  |           |
| Research & Related Personal Data   | Complete form as instructed  |           |

| Application Components   | Action   | Completed |
|--|--|-----------|
| Research & Related Senior/Key Person Profile (Expanded)              | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field                            |           |
|  | 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                                      |
| B        | Billion   |
| CDMRP    | Congressionally Directed Medical Research Programs  |
| CFR      | Code of Federal Regulations   |
| DOD      | Department of Defense   |
| DoDGARs  | Department of Defense Grant and Agreement Regulations                                     |
| eBRAP    | Electronic Biomedical Research Application Portal   |
| EC       | Ethics Committee  |
| ET       | Eastern Time  |
| FAD      | Funding Authorization Document  |
| FAPIIS   | Federal Awardee Performance and Integrity Information System                              |
| FY       | Fiscal Year   |
| IACUC    | Institutional Animal Care and Use Committee   |
| IDA      | Idea Development Award  |
| IRB      | Institutional Review Board  |
| LOI      | Letter of Intent  |
| M        | Million   |
| MB       | Megabytes   |
| MIPR     | Military Interdepartmental Purchase Request   |
| 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.  |
| 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 Department of Veterans Affairs