

# **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Prostate Cancer Research Program**

**Physician Research Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-21-PCRP-PRA**

**Catalog of Federal Domestic Assistance 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 17, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, July 1, 2021
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, July 7, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, July 7, 2021
- **Peer Review:** August 2021
- **Programmatic Review:** October 2021

*This program announcement must be read in conjunction with the General Application Instructions, version 603. 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 2021 (FY21) Prostate Cancer Research Program (PCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP). The PCRP was initiated in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY20 totaled \$1.93 billion. The FY21 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.

#### II.A.1. FY21 PCRP Overarching Challenges

The Mission of the FY21 PCRP is to fund research that will lead to the elimination of death 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 FY21 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 quality of life for the cancer survivor, their family, 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 treatments that 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, very high-risk, and metastatic prostate cancer. 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 the 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 lethal prostate cancer to reduce death**

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

## **II.B. Award Information**

The FY21 PCRP Physician Research Award supports a mentored research experience to prepare physicians with clinical duties and/or responsibilities for productive careers in prostate cancer research. The mentored physician is considered the Principal Investigator (PI) of the application. This award emphasizes equally the quality of the proposed research project and the career

development of the PI, which should prepare physicians for careers in basic, population science, translational, or clinical prostate cancer research. ***All applications for the FY21 PCRP Physician Research Award are to be written by the PI, with appropriate direction from the mentor(s).***

**Key elements of this award mechanism are as follows:**

- **Principal Investigator:** Physicians with clinical duties and/or responsibilities who, at the application submission deadline, are either in the last year of an accredited graduate medical education program as a resident or fellow, or within 5 years of having initiated a faculty appointment (including Instructor positions), are eligible to apply. The PI must demonstrate a commitment to a career as an investigator at the forefront of prostate cancer research and clinical practice; however, the PI is not required to have previous prostate cancer research experience. The award is intended to provide protection of the PI's time for prostate cancer research. Applications are strongly encouraged to demonstrate protection of at least 40% of the PI's time for prostate cancer research, which is not required to be exclusive to this award but can include effort dedicated to other prostate cancer research projects.
- **Mentor(s):** This award requires the involvement of at least one designated mentor with an established research program in prostate cancer, as evidenced by recent publications, active funding, and successful mentorship. In addition, the mentor(s) must demonstrate a commitment to advancing the PI's career in prostate cancer research.
- **Research Approach:** Proposed research ideas are ***required*** to address one or more of the [FY21 PCRP Overarching Challenges](#). The scientific rationale and experimental methodology should demonstrate in-depth analysis of the research problem presented. The feasibility of the research design and methods should be well defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved. The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the PI, mentor(s), or member(s) of the collaborating team. Additionally, required resources should be identified and supported through documentation.
- **Researcher Development Plan:** An individualized researcher development plan is required and should be prepared with appropriate guidance from the mentor(s). The researcher development plan should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise that will enable the PI to successfully complete the proposed research project and foster the PI's development as an independent prostate cancer researcher. An environment appropriate to the proposed mentoring and research project must be clearly described, although any deficiencies of resources and/or mentorship at the PI's institution can be mitigated through collaboration(s) with other institutions. If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-mentor at the collaborating institution.
- **Impact:** The proposed research must address and provide a solution to one or more of the [FY21 PCRP Overarching Challenges](#) and ultimately should have the potential to make a significant impact on the program's Mission of eliminating death 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.

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

***Research involving human subjects is permitted under this funding opportunity, but is restricted to studies without clinical trials.*** Correlative studies associated with an existing clinical trial are particularly encouraged, provided they are determined to be no greater than minimal risk by the Institutional Review Board (IRB) of record and the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO).

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 stage and recurrent patients. As a member of the Metastatic Cancer Task Force, the CDMRP encourages applicants to review the recommendations (<https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research>) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY21 PCRP priorities.

***The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.*** 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 FY21 PCRPA Physician Research Award will not exceed \$750,000. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

***The CDMRP expects to allot approximately \$7.2M to fund approximately six FY21 PCRPA Physician Research Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.***

#### **Research Involving Human Anatomical Substances, Human Subjects, or Human**

**Cadavers:** All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC ORP HRPO 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 submission is *not* required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research is cooperative (i.e., involving more than one 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 is defined*** as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. Note: Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical

research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

***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 placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

**Use of DOD or Department of Veterans Affairs (VA) Resources:** If the proposed research involves access to active-duty military 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 DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP 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 (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at [http://www.elsevier.com/\\_data/promis\\_misc/622936arrive\\_guidelines.pdf](http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf).

## **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 organization 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: 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.***

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

### **II.C.1.b. Principal Investigator**

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

In the last year of an accredited graduate medical education program, either as a resident or fellow, ***or***

Within 5 years of having initiated their first faculty appointment (including instructor positions).

Each investigator may be named on only one FY21 PCRP Physician Research Award application as a PI.

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

The CDMRP 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).***

### ***Extramural Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://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](http://eBRAP.org).
- Full application packages must be accessed and submitted at [eBRAP.org](http://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.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

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

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

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

***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process.*** Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application

in eBRAP. If any changes need to be made, the applicant should contact the CDMRP 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 CDMRP 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 and mentor(s) 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 CDMRP 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.

[FY21 PCR 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 CDMRP 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.

- **List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for three individuals who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter. The three letters of recommendation must include one from the mentor and two from the co-mentor(s) (if applicable) or other independent researchers who have had scientific knowledge and interaction with the PI.

- **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://www.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 W81XWH-21-PCRP-PRA from Grants.gov ( <a href="https://www.grants.gov/">https://www.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 W81XWH-21-PCRP-PRA 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.	<b>Tab 1 – Summary:</b> Provide a summary of the application information. <b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> </ul>	<b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP.

Extramural Submissions	Intramural DOD Submissions
<ul style="list-style-type: none"> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <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> <li>• <a href="#">Additional Application Component(s)</a></li> </ul>	<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="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> <li>• <a href="#">Other</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> 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><b>Note:</b> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget 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>
<b><u>Application Verification Period</u></b>	
<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</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</p>

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

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

**Attachments:**

*Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.*

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances.



Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (eight-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 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. *The Project Narrative must be written by the PI while also showing evidence of appropriate direction from the mentor(s).*

- **Principal Investigator:** The application should describe the PI’s career goals, demonstrating a strong personal commitment to pursuing an independent career as a leader at the forefront of prostate cancer research and patient care. Describe how the proposed research project and mentoring experience will promote the PI’s development toward becoming an independent prostate cancer physician-scientist. The application should discuss the PI’s career plans and research plans after the completion of this award.
- **Mentor(s):** Describe each mentor or co-mentor’s background and experience in prostate cancer research. Explain how the mentor(s) will assist the PI throughout the period of performance in developing toward independence in prostate cancer research. Provide details on the amount and types of interactions between the mentor(s) and the PI. Describe the track record of each mentor for mentoring young investigators in prostate cancer research.
- **Research Project:** Describe the proposed research project, including the background, hypothesis/objective, specific aims, experimental design, methods, and analyses. The application must provide a sound scientific rationale for the proposed project and its feasibility as established through a critical review and analysis of published literature and/or logical reasoning. Preliminary data are not required, but may be included to support the scientific rationale and feasibility of the research approaches. Include a statistical analysis plan for the proposed research and a power analysis to support the design and sample size (if applicable). Address potential problem areas and present alternative methods and approaches. Describe how the clinical relevance of the anticipated findings will be determined, if applicable. Explain how cell line authentication and/or statistical rigor of preclinical experiments have been incorporated into the study design, if applicable. For clinical research, see [Attachment 9](#) for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.
- **Overarching Challenges:** Briefly describe how the proposed research will help address and provide a solution to one or more of the [FY21 PCRP Overarching Challenges](#).



- **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 or not 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, indicating the level of organizational commitment to fostering the PI’s research and clinical career, and confirming the laboratory space, equipment, and other resources available for the project. The letter should also reflect the extent to which the PI’s clinical or other responsibilities will be adjusted to secure additional time for research. Protection of at least 40% of the PI’s time for prostate cancer research, which is not required to be exclusive to this award but can include effort dedicated to other prostate cancer research projects, is strongly encouraged. 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 that will demonstrate 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.
- **Transcripts:** Include a copy of the PI's transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), provide an academic statement signed by an appropriate organizational official that includes the following information about the PI's academic performance: organization name (medical or graduate); degree earned; date (month/year) the PI completed requirements for degree; the PI's overall grade point average or academic ranking; any other information that attests to the PI's academic performance (e.g., courses completed; grades/scores/honors earned by the PI).
  - **Intellectual Property:** Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (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.
  - **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:

– **Research Plan**

- **Background:** Present the ideas and reasoning behind the proposed work.
- **Objective/Hypothesis:** State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design including appropriate controls.

– **Personnel**

- The PI’s career goals and potential for a career at the forefront of prostate cancer research and patient care.
- The strategy for acquiring necessary skills, competence, and expertise to successfully complete the proposed research project.
- The mentor’s (and co-mentor’s, if applicable) background and experience in prostate cancer research and proposed contribution to the career development of the PI.
- How the proposed research project will prepare the PI to make valuable contributions to the understanding and clinical management of prostate cancer.

- **Impact:** Summarize how the proposed research will address and provide a solution to one or more of the [FY21 PCRP Overarching Challenges](#) and ultimately provide progress toward eliminating death 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.** 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.

- Describe the scientific objective and rationale for the proposed research project in a manner that will be **readily understood by readers without a background in science or medicine.**
- Describe the ultimate applicability of the research.
  - What are the likely contributions of this study to the [FY21 PCRP Overarching Challenges?](#)
  - What types of patients will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
  - If the research is too basic for near-term clinical applicability, describe the interim outcomes.
- Describe the PI’s career goals in prostate cancer research and patient care.
  - How does the research plan support the PI in achieving these goals?
  - How do the mentorship and researcher development plan support the PI in achieving these goals?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** 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 FY21 PCRP Physician Research 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: Researcher Development Plan (one-page limit): Upload as “ResearchDev.pdf”.**
  - Clearly articulate an *individualized strategy* that will enable the PI to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project.
  - Indicate how the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of prostate cancer, and effectively prepare the PI for a career as an independent prostate cancer physician-scientist.
  - Describe how the researcher development plan is supported by the environment and mentorship, including a description of ongoing prostate cancer research at the institution. Include a description of the environment of any collaborating institutions that will augment the lack of specific resources at the PI’s primary institution (if applicable). If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-mentor at the collaborating institution. Include information on collaborations with other investigators, seminars, workshops, and other opportunities for professional interaction with leaders in the prostate cancer field. *Members of the [FY21 PCRP Programmatic Panel](#) must not be involved.*
- **Attachment 7: Impact Statement (one-page limit): Upload as “Impact.pdf”.**

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

  - ***Describe the short-term impact:*** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research, including any clinically relevant results. Summarize how the anticipated outcome(s)/product(s) address(es) and will help provide a solution to one or more of the [FY21 PCRP Overarching Challenges](#).
  - ***Describe the long-term impact:*** Explain the anticipated long-term gains from the proposed research. Describe how the anticipated long-term gains would make a major impact on prostate cancer research and/or patient care, and ultimately contribute to the goal of eliminating death 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 8: Eligibility Statement (one-page limit): Upload as “Eligibility.pdf.”**

Provide a letter, signed by the PI and the Department Chair, Dean, or equivalent official, verifying that the eligibility requirements have been met by the application submission deadline. If the PI is in the last year of an accredited graduate medical education program, either as a resident or fellow, provide the date (month/year) the PI will complete their medical residency or fellowship. For PIs with a faculty appointment, provide the

date (month/year) the PI began the appointment to verify that he/she is within 5 years of having initiated their first faculty appointment (including Instructor positions).

- **Attachment 9: Inclusion of Women and Minorities (four-page limit): Upload as “Inclusion.pdf”.** (*Attachment 9 is only applicable and required for applications that propose clinical research.*) Describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. The suggested Inclusion Enrollment Report format, Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
  - **Attachment 10: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
  - **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or 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 mentor’s (and co-mentor’s, if applicable) biographical sketch.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - Include mentor’s (and co-mentor’s, if applicable) previous/current/pending support.

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

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

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

- **Extramural Applications Only**

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

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

<b>Additional Application Components</b>
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In addition to the complete application package, FY21 PCRP Physician Research Award applications also require the following components:

- **Three Confidential Letters of Recommendations**

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

The confidential letters should include the following (two pages per letter recommended):

*The confidential letter of recommendation from each mentor* should include a description of the mentor’s commitment to the PI’s career development, mentorship in prostate cancer research, and ability to supervise the PI’s research project. Mentor letters should also address the following:

- The PI’s potential to become a successful and independent prostate cancer researcher in addition to continuing practice as a physician
- Details of the proposed interactions of each mentor with the PI during the PI’s research project
- The mentoring environment, including ongoing prostate cancer research in the mentor’s and co-mentor’s (if applicable) laboratory and in the organization as a whole, resources available, and how this environment will promote the development of the PI as a prostate cancer researcher
- The degree to which the PI participated in the project development and application preparation, and the degree to which the PI will participate in the execution of the application if funded

***Additional confidential letters of recommendation:*** The remaining letter(s) should describe the PI’s unique qualifications and accomplishments that highlight their potential for success



as a prostate cancer researcher and clinician. Specifically, each letter should offer the writer's perspective on:

- The PI's qualifications, characteristics, and achievements
- The PI's potential for productivity and desire for establishing a successful and independent career in prostate cancer research and patient care
- The relevance of the proposed research project to preparing the PI for a career in prostate cancer research
- The suitability of the mentor(s) and the research environment for providing the PI with a solid foundation to support an independent career in prostate cancer research

### **II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)**

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Verify the status of the applicant organization's Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

*Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI):* Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

### **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 **4** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the government exceeding **\$750,000** 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 **4** years.

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

- Travel in support of multidisciplinary collaborations
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting is to present project information or disseminate project results from the FY21 PCRP Physician Research Award
- Up to 50% combined salary support for one or two support personnel (e.g., laboratory technician, research nurse, data manager)
- Clinical research costs
- Workshop costs

Must not be requested for:

- Clinical trial costs
- Equipment
- Salary support for the mentor(s) or any other senior personnel except the PI

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

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

## **II.D.6. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

## **II.E. Application Review Information**

### **II.E.1. Criteria**

#### **II.E.1.a. Peer Review**

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

- **Principal Investigator**

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

- **Mentor(s)**

- Whether there is at least one mentor who is an established prostate cancer researcher, as evidenced by a demonstrated record of active funding and recent publications in prostate cancer research
- How well the mentor's (and co-mentor's, if applicable) own experience in prostate cancer research and their ongoing research program and available resources support the ability to supervise the PI's research project
- To what extent the track record(s) of the mentor(s) in previously mentoring young investigators indicate the potential for successful mentoring of the PI in prostate cancer research
- Whether the mentor letter(s) indicate a high level of commitment to the PI's development as an independent prostate cancer researcher
- Whether the quality of the application suggests that the mentor(s) provided appropriate guidance in its preparation

- **Research Project**

- How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data (if included), and/or logical reasoning
- Whether the experimental design and the statistical analysis plan, if applicable, are appropriate for the research proposed
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed

- How well the application acknowledges potential problems and addresses alternative approaches
- As applicable, how well the application describes components to increase the impact of the project, including cell line authentication, statistical rigor of preclinical experiments, and/or experiments to address clinical relevance
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research
- If applicable, to what degree the intellectual and material property plan is appropriate
- **Researcher Development Plan and Environment**
  - How well the application outlines an individualized researcher development plan that will enable the PI to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project
  - How well the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in prostate cancer research, and effectively prepare him/her for a career as an independent prostate cancer physician-scientist
  - To what extent the scientific environment at the primary institution (and collaborating institution(s), if applicable) is appropriate for the proposed research and career development activities, including availability of professional interaction with established prostate cancer researchers
  - To what degree the organizational commitment to adjust the PI's clinical or other responsibilities to secure additional time for research will help foster the PI's research and clinical career
  - To what extent the research requirements are adequately supported by the availability and accessibility of facilities and resources (including collaborative arrangements and/or intellectual property plans as applicable)
- **Impact**
  - To what degree the anticipated outcome(s)/product(s) of the project will address and provide a solution to one or more of the [FY21 PCRP Overarching Challenges](#)
  - To what degree the proposed research would, in the long term, make a major impact on prostate cancer research and/or patient care, and contribute to the goal of eliminating death 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
  - To what degree the proposed research project and mentoring experience will bring the PI to the forefront of prostate cancer research and patient care

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
- **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 DHP and FY21 PCRCP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Programmatic relevance to the [FY21 PCRCP Overarching Challenges](#)
  - Relative impact

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

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). ***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.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the PCRCP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

### **II.E.3. Integrity and Performance Information**

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, 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 FY21 funds are anticipated to be made no later than September 30, 2022. 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 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 other 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](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the



[USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

### **II.F.3. Reporting**

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

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

The Award Terms and Conditions will specify if more frequent reporting is required.

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

Awards resulting from this program announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10.0M are required to provide information to 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. 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. CDMRP 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 CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. 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 CDMRP 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 603b. The program announcement numeric version code will match the General Application Instructions version code 603.

### **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.
- More than one application is received naming the same investigator as a PI. Only the first application received will be accepted; additional applications will be administratively rejected.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

#### **II.H.2.b. Modification**

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

### II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY21 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 FY21 PCRP Programmatic Panel members can be found at <https://cdmrp.army.mil/pcrp/panels/panel21>.*
- 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 FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The application does not address at least one of the [FY21 PCRP Overarching Challenges](#).

### II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to

provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

### II.H.3. 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"	
	Researcher Development Plan: Upload as Attachment 6 with file name "ResearchDev.pdf"	
	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf"	
	Eligibility Statement: Upload as Attachment 8 with file name "Eligibility.pdf"	
	Inclusion of Women and Minorities: Upload as Attachment 9 with file name "Inclusion.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

<b>Application Components</b>	<b>Action</b>	<b>Completed</b>
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 ( <b>extramural submissions only</b> )	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget ( <b>intramural submissions only</b> )	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	
<b>Additional Application Components</b>	<b>Action</b>	<b>Completed</b>
Confidential Letters of Recommendation	Confirm upload to eBRAP	

## 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
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
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
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PCRP	Prostate Cancer Research Program
PI	Principal Investigator
PRA	Physician Research Award
RDT&E	Research, Development, Test, and Evaluation
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