

# **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**

**Clinical Consortium Award**

**Announcement Type: Initial**

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

**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), September 2, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, September 23, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, September 28, 2021
- **Peer Review:** November 2021
- **Programmatic Review:** January 2022

*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.A.2. Award History**

The PCRCP Clinical Consortium Award mechanism was first offered in FY05 and again in FY06, FY08, FY13, and FY17. In FY16, the Clinical Consortium Research Site Award was offered.

## II.B. Award Information

The Clinical Consortium Award mechanism provides the support to develop and enhance collaborations and resources necessary for a network of organizations to rapidly execute phase 2 or phase 2-linked phase 1 (phase 1/2) prostate cancer clinical trials. These trials will include investigations of high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer as pertaining to the [FY21 PCRP Overarching Challenges](#). Support from this award is directed toward consortium infrastructure needs rather than direct support of the research itself.

The principal goal of the Clinical Consortium Award is to combine the efforts of leading investigators to bring to market high-impact, novel therapeutic interventions that will ultimately and significantly decrease the impact of the disease. To facilitate global investigations, Principal Investigators (PIs) from both U.S. and international institutions are encouraged to apply. ***Submissions from institutions with enhanced access to patients from high-risk, underserved, and/or military populations (as described in the FY21 PCRP Overarching Challenges) are especially encouraged.***

The FY21 PCRP Clinical Consortium Award mechanism will be used to select and fund approximately 10 Clinical Research Sites and one Coordinating Center. ***NEW FOR FY21: In addition, the consortium will include two or more identified Affiliated Clinical Research Sites to be supported and managed by the Coordinating Center. Affiliated Clinical Research Sites should have enhanced access to patients from high-risk, underserved, and/or military populations.***

PIs will be required to indicate whether the institution is applying as either the Coordinating Center with a Clinical Research Site or a Clinical Research Site only. Institutions applying as the Coordinating Center, if not selected for funding, have the option to still be considered as a Clinical Research Site only. The Coordinating Center and Clinical Research Sites will be jointly responsible for proposing, selecting, and conducting phase 2 and phase 1/2 clinical trials focused on prostate cancer therapeutic interventions. Additional details regarding the structure of the consortium are described in detail below.

The Coordinating Center, in addition to functioning as a Clinical Research Site, will serve as the consortium information and planning nexus providing administrative, operational, and data management support services to participating Clinical Research Sites to implement consortium clinical trials in a timely manner. Responsibilities of the Coordinating Center will include the clinical trial selection process, protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, and intellectual/material property coordination. The Coordinating Center will also be responsible for preparing two clinical trials, with funding already secured, to be initiated by the consortium within the first 3 months of the performance period. ***All sites (Clinical Research Sites and the Coordinating Center) will be required to participate in at least one of these two initial clinical trials.***

Collectively, the Coordinating Center PI and Clinical Research Site PIs will constitute the Clinical Consortium Committee, which will collaboratively develop and maintain a procedure for the selection of clinical trials to be implemented within the consortium. A representative from the PCRP must be invited to meetings of the Clinical Consortium Committee, as well as any other formal meetings of the consortium. All sites will be responsible for working collaboratively to identify new clinical trials for implementation. Any site may serve as an entry point for clinical trials that originate from outside the consortium. The Coordinating Center will be responsible for facilitating this entire process.

Key requirements of the Clinical Consortium Award include:

- **Responsibilities of the Consortium Participants:** Procedures for the consortium, while proposed by the Coordinating Center, will be fully developed and agreed upon by all participants working collaboratively. All references to clinical trials in the outlined responsibilities are specific to phase 2 or phase 1/2 trials; phase 3 or higher clinical trials are not included. At the discretion and expense of the government, a pre-award planning meeting may be required.
  - **Coordinating Center:** Responsibilities specific to the Coordinating Center include:
    - Adherence to the responsibilities delineated below for a Clinical Research Site.
    - Coordination and facilitation of at least 12 clinical trials at any given time after the first 12 months of the performance period.
    - Development and execution of plans for the incorporation, support, and involvement of no fewer than two Affiliate Clinical Research Sites (of U.S. or international origin) intended to enhance the impact of the consortium by contributing unique patient populations to consortium trials, including those from high-risk, underserved, and/or military populations (as described in the [FY21 PCRP Overarching Challenges](#)). The Coordinating Center will establish performance metrics for Affiliate Clinical Research Sites, which should emphasize higher accrual rates for the unique patient population(s) the site has enhanced access. *The government reserves the right to request the identification of alternative Affiliate Clinical Research Sites prior to award if those identified in the application do not demonstrate sufficient access to identified patient populations.*
    - Development and maintenance of the consortium organizational structure.
    - Provision of at least two initial clinical trial protocols for implementation by the consortium within the first 3 months of the performance period.
    - Management of consortium-developed procedures for review, selection, and implementation of clinical trials proposed by or through consortium members.
    - Establishment and management of procedures to ensure compliance with the local Institutional Review Boards (IRBs) of all sites for the conduct of clinical trials and the protection of human subjects.

- Establishment and management of procedures for ensuring compliance with Food and Drug Administration (FDA) requirements for investigational agents, devices, and procedures.
- Establishment and management of a communications plan and an ongoing communications system between the Coordinating Center and Clinical Research Sites.
- Management of consortium-developed quality assurance and quality control mechanisms for study monitoring, including:
  - Real-time and remote monitoring program
  - Management plan for the handling, distribution, analysis, and banking of specimens and/or imaging products generated from consortium studies necessary for the conduct and analyses of clinical trials during the performance period of the award
  - Registration, tracking, and reporting of participant accrual
  - Timely medical review and assessment of participant data
  - Rapid reporting and communication of adverse events
  - Interim evaluation and consideration of measures of outcome
- Management of consortium-developed comprehensive data collection and data management systems that addresses the needs of all sites in terms of access to data, data security, and data integrity measures.
- Development of statistical plans for all consortium clinical trials.
- Management of consortium-developed intellectual and material property issues among institutions participating in the consortium.
- Management of consortium-developed procedures for the timely publication of major findings and other public dissemination of data.
- Development and execution of a plan for financial sustainability leveraging collaborations, industry sponsors, and/or other funding opportunities to allow consortium activities to continue beyond the award period of performance.
- Presentation of written and/or oral briefings to the PCRP Programmatic Panel and U.S. Army Medical Research and Development Command (USAMRDC) staff at 1-day meetings typically held in the Baltimore-Washington, DC area.

- **Clinical Research Sites:** The responsibilities of each site include:
  - If required by the government, participation in a pre-award planning meeting with all consortium members to discuss operational features of the consortium, the requirements for progress and evaluation, and the award negotiations process.
  - Full participation in the consortium, including but not limited to, clinical trial introduction and selection, patient accrual for consortium studies (to include accrual from high-risk, underserved, and/or military populations), data collection and timely submissions, meeting attendance, and adherence to the consortium’s operating procedures.
  - Presentation of at least two clinical trials for the consortium’s consideration per year. *For the Coordinating Center, this requirement is in addition to the initial two clinical trials required at the beginning of the award.*
  - Meeting minimum accrual requirements of 25 patients per year, either independently or in partnership with other non-consortium institutions. At least 20% of these patients must be contributions to trials from other consortium sites, and at least 5% of all accrued patients at each site must be from high-risk, underserved, and/or military populations.
  - Provision for a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other Clinical Research Sites and the Supervising Clinical Research Coordinator of the Coordinating Center to expedite and guide clinical protocols through the regulatory approval processes and to coordinate patient accrual and study activities across sites.
  - Implementation of the consortium’s core data collection methodology and strategies.
  - Compliance with consortium-developed quality assurance and quality control procedures, as appropriate, including:
    - Participation in a monitoring program to be managed by the Coordinating Center.
    - Implementation of the consortium-developed management plan for acquisition, delivery, and storage of biological samples and study data.
    - Submission of appropriate data and materials to allow for verification and review of protocol-related procedures, for example, pathology, imaging techniques, surgical methods, and therapeutic use.
  - Implementation of procedures established by the Coordinating Center for ensuring compliance with FDA requirements for investigational agents, as appropriate.
  - Implementation of procedures established by the Coordinating Center to meet the local IRB requirements for the conduct of clinical trials and the protection of human subjects.

- Serving as a resource for the conduct of protocol-specified laboratory projects (such as tumor biology studies).
  - Participation in consortium-developed procedures for the timely publication of major findings.
  - Participation in consortium-developed procedures for resolving intellectual and material property issues among institutions participating in the consortium.
  - Submission of annual written progress reports, a final written comprehensive report, and any other reports required by the government to be outlined in the assistance agreement.
  - Additional responsibilities based on recommendations and guidance from the USAMRDC staff.
- **Performance Metrics:** The Clinical Consortium Award recipients will be accountable to the following performance metrics, upon which continued funding will be contingent after the first 12 months of the award. All references to clinical trials in the outlined responsibilities are specific to phase 2 or phase 1/2 trials; phase 3 or higher clinical trials are not included.
    - **Metrics for Coordinating Center Performance:**
      - Completion of at least four trials in the initial 12-month period of the award period of performance.
      - Maintain a portfolio of at least 12 open trials at any given time after the first 12 months of the period of performance.
      - Successfully move agents for at least 20% of consortium trials forward for additional testing (e.g., phase 3), which ultimately have the potential to change clinical practice. **Note:** The Clinical Consortium Award is not intended to support the conduct of clinical trials that test the next logical iteration of an existing treatment.
      - Enrollment of at least 5% of patients from high-risk, underserved, and/or military populations (as described in the [FY21 PCRP Overarching Challenges](#)) in consortium trials overall.
    - **Metrics for Clinical Research Site Performance:**
      - Accrual of at least 25 patients per year to consortium trials, either independently or in partnership with other non-consortium institutions. At least 20% of these patients must be contributions to trials from other consortium sites.
      - Participation in a minimum of eight trials initiated by other consortium sites over four years.

- Presentation of at least two trials per year or eight trials over four years to the consortium for consideration.
  - Accrual of at least 5% of patients from high-risk, underserved, and/or military populations (as described in the [FY21 PCRP Overarching Challenges](#)).
  - Timely submission of quality data as outlined by the Coordinating Center.
- **Plan for Financial Sustainability:** It is expected that the collaborations and infrastructure developed under the Clinical Consortium Award will continue past the period of performance on this award. Coordinating Center applications must include a plan for financial sustainability that leverages collaborations, industry sponsors, and/or other funding opportunities to allow consortium activities to continue beyond the award period of performance.
  - **Past Performance (if applicable):** Applications from institutions that have previously received a PCRP Clinical Consortium Award must include a description of the past performance of the award, including compliance with the metrics of the previous award as well as other individual contributions made to consortium activities. If past performance was directly affected by the COVID-19 pandemic, and/or other significant event (e.g. natural disaster), describe its impact on performance metrics and how those issues will be resolved or mitigated to increase performance for the new award.

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 DOD during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, 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 which is of significance to the warfighter, military families, and the American public.

The PCRCP plans to invest \$30.72M in the Clinical Consortium Award over a 4-year period. A total of \$7.68M will be allocated from the FY21 budget to fund the first year of performance. Options will be included for continued performance in subsequent years with \$7.68M expected from each of the FY22-FY24 budgets to fund the options. The initial performance period of the award and each option period will be for 12 months. ***Exercise of the options for continued performance is contingent on receipt of sufficient congressional appropriations to the PCRCP in FY22-FY24 and acceptable performance by the recipients.*** The anticipated direct costs budgeted for the entire period of performance for an FY21 PCRCP Clinical Consortium award will not exceed **\$7.2M for the Coordinating Center or \$1.2M for each Clinical Research Site.** 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 \$7.68M to fund approximately one Coordinating Center and approximately 10 Clinical Research Site Clinical Consortium 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 initially funded with FY21 funds, which will expire for use on September 30, 2027.***

***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.

**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.

## **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**

Independent investigators with a faculty-level appointment (or equivalent). Eligibility is not affected by previous receipt of a PCRCP Clinical Consortium Award.

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](http://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](http://eBRAP.org)) and *full application* ([eBRAP.org](http://eBRAP.org) or [Grants.gov](http://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.

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

- ***Clinical Consortium Award – Clinical Research Site, or***
- ***Clinical Consortium Award – Coordinating Center***

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

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the 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 PCRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the 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.

- **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**

<b>Extramural Submissions</b>	<b>Intramural DOD Submissions</b>
<b>Application Package Location</b>	
Download application package components for W81XWH-21-PCRP-CCA 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-CCA from eBRAP ( <a href="https://ebrap.org/">https://ebrap.org/</a> ).

Extramural Submissions	Intramural DOD Submissions
<b>Full Application Package Components</b>	
<p><b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> </ul>	<p><b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>

Extramural Submissions	Intramural DOD Submissions
<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><a href="#">Application Verification Period</a></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 application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b> Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>

Extramural Submissions	Intramural DOD Submissions
<b>Further Information</b>	
<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 (60-page limit for the Coordinating Center plus Clinical Research Site; 20-page limit for each Clinical Research Site): 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.

- **Coordinating Center (40-page limit):** The application should clearly articulate the ability of PI's group to serve as the consortium Coordinating Center and support the design and conduct of consortium clinical trials.

Describe the qualifications of the group and plans for the development of key features of the consortium Coordinating Center using the following general outline:

- **Commitment to and Experience in Multidisciplinary and Multi-Institutional Prostate Cancer Clinical Research:** Describe previous experience and accomplishments related to the design, administration, and fiscal management of multi-institutional prostate cancer clinical trials, with particular emphasis on phase 2 trials of high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer. Describe previous experience with establishing communications systems and data management resources for multi-institutional projects. Reference relevant publications and submit reprints with the application. If the institution is a previous recipient of a PCRP Clinical Consortium Award, whether as Coordinating Center or Clinical Research Site, a description of the past performance of that award must be included.
- **Institutional Resources:** Provide evidence of institutional commitment to provide the necessary resources needed to develop and support standardized data collection, data management and analysis, and data security and integrity for the consortium participants.
- **Consortium Organizational Structure:** Provide a detailed description of the overall consortium organization, plans for ongoing communications, procedures for transference of funds, and standardized operating procedures for selection and implementation of clinical trials. The organizational structure should include the following key features:
  - ❖ Coordinating Center for administration and day-to-day management of consortium operations; developing the clinical trial selection process, protocol coordination; regulatory coordination; study management and monitoring; data collection, management, and statistics; intellectual/material property coordination; and performance as a Clinical Research Site.
  - ❖ Clinical Research Sites for conceiving, developing, and conducting clinical trials in prostate cancer, as well as serving as entry points for clinical trials from outside the consortium.
  - ❖ Clinical Consortium Committee composed of the PIs from the Coordinating Center and Clinical Research Sites, for the clinical trial selection process and for the continual development and operation of the consortium. A representative from the USAMRDC is to be invited to all official meetings for the Clinical Consortium Committee.
  - ❖ Plans for ongoing communications among Clinical Research Sites and between Clinical Research Sites and the Coordinating Center that will enable

them to function as an integrated unit; plans should address methods for information distribution within the consortium, and how information technologies will be used to (1) facilitate routine multi-institutional communication and (2) provide ongoing communication and data sharing.

- **Affiliate Clinical Research Sites:** Identify the institutions that are proposed to be incorporated into the consortium as Affiliate Clinical Research Sites and provide the rationale for their selection. Describe the plan for supporting the affiliate sites and incorporating them into consortium activities. Describe the available prostate cancer patient population (including size, age range, and clinical manifestations) at the identified sites, with emphasis on patients from high-risk, underserved, and/or military populations. Provide evidence of each site's prior success in recruiting patients for clinical trials, emphasizing any unique populations, and provide examples of prior successful multi-center clinical trial collaborations. Outline the performance metrics the Affiliate Clinical Research Sites will be expected to achieve, with an emphasis on higher accrual rates for the unique patient population(s) the site has enhanced access to.
- **Clinical Trials Implementation:** Describe plans for coordinating the submission, review, selection, and implementation of clinical trials within the consortium.
  - ❖ Outline plans for coordinating IRB submissions and approvals at participating sites.
  - ❖ Outline plans for developing procedures to ensure compliance with FDA requirements for investigational agents, as appropriate.
- **Study Management and Monitoring:** Describe plans for ongoing communication among all institutions participating in the consortium.
  - ❖ Include a **named** Supervising Clinical Research Coordinator; describe how their prior experience will support their ability to interact with and oversee the Clinical Research Coordinators located at other consortium sites in order to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites.
  - ❖ Outline procedures for quality assurance, quality control, and study monitoring.
  - ❖ Describe plans for the development of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from consortium-sponsored studies.
- **Data Management:** Outline a strategy for the development and implementation of a comprehensive data management and statistical analysis plan that will provide access to data, data security, and data integrity, including:

- ❖ Descriptions of the overall approach to data collection and management.
- ❖ A statistical plan that includes methods to monitor quality and consistency of data collection and methods to measure outcomes.
- ❖ A plan for ongoing data transfer.
- ❖ Data security and integrity measures.
- **Publication and Data Dissemination:** Describe plans for ensuring rapid publication and other public dissemination of data; address potential privacy issues of study participants.
- **Fiscal Administration:** Describe previous experience with acquiring funding for clinical trials, and with the financial management of multi-institutional clinical research studies. Outline a detailed strategy for achieving financial sustainability that leverages collaborations, industry sponsors, and/or other funding opportunities to allow consortium activities to continue beyond the award period of performance.
- **Two Initial Clinical Trials: Start section on a new page; 10-page limit for this section within the 40-page limit for the Coordinating Center portion.** Provide brief descriptions of two currently funded phase 2 or phase 1/2 prostate cancer clinical trials proposed to be implemented by the consortium within the first 3 months of the award period. It is expected that most, if not all, of the patients for these studies will be accrued from within the consortium. Therefore, the two initial clinical trials must be ready to initiate patient accrual just prior to or at the initiation of the award, as demonstrated by the proposed timelines and regulatory and funding status for each trial requested below.

Include the following information for each of the two proposed clinical trials:

- ❖ Clinical trial title: Provide the title of each clinical trial.
- ❖ Phase: Designate the clinical trial as phase 1/2 or 2.
- ❖ Personnel: List the names of all personnel (including the PI) who will have significant involvement in the clinical trials; include their practice license(s) (e.g., M.D. or R.N.), highest degree(s), job title(s), and employing institution(s). Describe any relevant expertise the research team has in conducting and completing prostate cancer clinical trials.
- ❖ Location of study: List all centers, clinics, or laboratories where the studies are to be conducted; include details as to how consortium Clinical Research Sites will be integrated into these trials.

- ❖ **Background:** Describe the rationale for conducting the study, as well as the study's relevance and applicability of findings; include descriptions of preliminary studies, phase 1 results, or other findings.
  - ❖ **Objectives:** Describe the purpose, goals, and endpoint of the study.
  - ❖ **Drug or device:** Describe the drugs or devices to be used in the studies; describe how they meet the mechanism intent of supporting investigation of high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer. Include Investigational New Drug (IND)/Investigational Device Exemption (IDE) numbers, sponsors, and sources, if applicable. Describe the procedures that will ensure compliance with FDA regulations for investigational agents.
  - ❖ **Study population:** Describe the target population and the proposed sample size and provide patient accrual rate requirements. Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects, if applicable.
  - ❖ **Protocol design:** Describe the type of study to be performed (prospective, retrospective, randomized, controlled, etc.) and outline the proposed methodology. Include a description of the proposed timelines for the study, emphasizing points that demonstrate increased efficiency of the study as a result of consortium participation.
  - ❖ **Funding and IRB approval status:** Provide evidence of funding status of the initial clinical trial(s); describe the status of IRB approval for the initial clinical trial(s), including plans for the coordination of IRB submissions and approvals at participating sites.
  - ❖ **Impact:** Describe anticipated outcomes of the proposed study and the potential impact of the intervention or device, if successful, in addressing the [FY21 PCRP Overarching Challenges](#) and on prostate cancer patient care.
- **All Sites (Coordinating Center and Clinical Research Sites) (20-page limit):** The application should clearly articulate the qualifications of the research team and institution to support their ability to successfully integrate into the consortium as a Clinical Research Site and be a contributing member.

Provide evidence that the research team and institution fulfill each of the following criteria for participation in the consortium:

- **Commitment to and experience in prostate cancer clinical research**

If the institution is a previous recipient of an FY16 PCRP Clinical Consortium Research Site Award or FY17 PCRP Clinical Consortium Award, whether as

Coordinating Center or Clinical Research Site, a description of the performance of that award must be included, including performance related to the previous award metrics, and a description of the individual contribution(s) of the institution to consortium activities. If past performance was directly affected by the COVID-19 pandemic, and/or other significant event (e.g. natural disaster), describe its impact on performance metrics and how those issues will be resolved or mitigated to increase performance for the new award.

- ❖ Describe the PI's commitment to prostate cancer clinical research, which may include levels of effort, funding, and interactions with consumer advocacy groups.
  - ❖ Describe the experience of the PI and other key members of the research team in conducting collaborative, multi-institutional clinical trials that demonstrate willingness and ability to function in the consortium.
  - ❖ Describe the research team's ability and experience to contribute substantially to the design and conduct of consortium clinical trials. Describe specific areas of clinical research interest, such as novel drugs, combinatorial therapy schedules, surgical interventions, imaging techniques, and immunotherapies; explain the relevance and potential impact on the [FY21 PCRP Overarching Challenges](#). Include overall scope of program and demonstration of integration of basic and/or correlative science into the program.
  - ❖ Provide details of ongoing or completed prostate cancer-relevant clinical trials, particularly Phase II clinical trials, with an emphasis on clinical trials that might be brought into the consortium. Reference relevant publications and submit reprints with the application.
  - ❖ Describe procedures for ensuring compliance with FDA requirements for investigational agents.
  - ❖ Provide evidence of willingness to resolve intellectual and material property issues.
- **Consortium resources**
- ❖ Include a **named** institutional Clinical Research Coordinator who will interact with the Clinical Research Coordinators at other consortium Clinical Research Sites and the Supervising Clinical Research Coordinator at the Coordinating Center to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites. Describe the relevant experience of the named Clinical Research Coordinator to support their ability to fill this role.
  - ❖ Describe the available prostate cancer patient population(s) (including size, age range, and clinical manifestations) and provide evidence of ability to accrue prostate cancer patients into consortium-sponsored studies. Include

documentation of access to and ability to recruit patients from high-risk, underserved, and/or military populations.

- ❖ Provide evidence of success in recruiting patients for clinical trials, and examples of prior successful multi-center clinical trial collaborations.

- **Institutional resources**

- ❖ Provide evidence of expertise in clinical trials within the applicant institution and describe experience in the development and conduct of prostate cancer clinical trials; as appropriate, describe any additional multidisciplinary clinical and/or laboratory expertise that could serve as the basis for the development of clinical trials by the consortium.
- ❖ Describe the resources and expertise available for the collection and processing of specimens from consortium-sponsored studies.
- ❖ Describe the resources and expertise for data management and maintenance of data security/confidentiality.

Provide evidence of institutional commitment to facilitating collaborations, providing facilities and resources in the conduct of consortium operations, and describe any unique resources that may be of benefit to the consortium.

- **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, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization 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.
- **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.
  - *Note: As this award supports consortium infrastructure and does not provide direct support for the clinical research, certain types of intellectual property may not be relevant to this application and need not be discussed.*
  - **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.

- **Clinical Trial Funding and Approval Documentation (Coordinating Center applications only):** Provide documentation of funding and IRB approval status for the two initial clinical trials.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Inclusion of Women and Minorities (Coordinating Center only):** For each of the initial clinical trials described in the application, provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Describe the proposed consortium or, for Clinical Research Site applications, specific participation in the consortium including the following elements:

- **Background:** Present the ideas and reasoning behind the proposed effort.
- **Objective/Hypothesis:** State the objectives to be achieved. Provide evidence that supports the feasibility.
- **Specific Aims:** State the specific aims.
- **Study Design:** Briefly describe the types of clinical trials to be proposed for conduct by the consortium.
- **Clinical Impact:** Briefly describe how the proposed consortium, or participation in the consortium, may lead to a major impact on prostate cancer clinical management

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”, if applicable.** 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 is required for Coordinating Center applicants only. Lay abstracts 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 objectives and rationale for the proposed consortium 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 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 an impact on the standard of care for prostate cancer?
  - What are the likely contributions of this study to advancing the field of prostate cancer research and patient care?

- **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 Clinical Consortium Award mechanism, refer to the “***Suggested SOW Strategy Generic Research***” document for guidance on preparing the SOW and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** Explain in detail the anticipated impact of the applicant’s participation in the consortium, as follows:

***Describe the short-term impact:*** Explain how the research team’s areas of clinical research interest will support the presentation of clinical trials to evaluate high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer. Detail the anticipated outcomes from the institution’s participation in consortium-led clinical trials, including the potential impact the institution is expected to

have in recruiting patients from high-risk, underserved, and/or military populations to consortium-led studies. Explain how these results/outcome(s)/product(s) will have the potential to impact the [FY21 PCRP Overarching Challenges](#).

***Describe the long-term impact:*** Explain the long-term gains from the research team’s contributions to the consortium, including how the outcomes or products will ultimately contribute to the elimination of 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 7: Data and Research Resource Sharing Plan (one-page limit): Upload as “Sharing.pdf”.** Describe how unique and/or final research data will be shared with the wider prostate cancer research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the award. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data and/or research resource sharing plan.

Refer to the General Application Instructions, Appendix 2, Section K, for additional information.

- In preparing requested budgets, applicants may include anticipated costs associated with data and research resource sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community).
- **Attachment 8: 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 9: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, which is 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”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.

**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 9](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

### **II.D.3. 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 PCRCP plans to invest \$30.72M in the Clinical Consortium Award over a 4-year period. A total of \$7.68M will be allocated from the FY21 budget to fund the first year of performance. Options will be included for continued performance in subsequent years with \$7.68M expected from each of the FY22-FY24 budgets to fund the options. The initial performance period of the award and each option period will be for 12 months. ***Exercise of the options for continued performance is contingent on receipt of sufficient congressional appropriations to the PCRCP in FY22–FY24 and acceptable performance by the recipients.***

The purpose of the PCRCP Clinical Consortium Award is to provide the funding to establish the necessary collaborations and resources to rapidly execute clinical trials by the consortium. This award will not fund research or development of clinical protocols.

## Coordinating Center

- The expected period of performance is **4** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$7.2M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. These funds are for all Coordinating Center functions, administrative and clinical, and support for two or more Affiliate Clinical Research Sites as described in this program announcement. The proposed Coordinating Center budget must include no less than **\$250,000 per year** for *each* Affiliate Clinical Research Site (or a total of \$1,000,000 for each Affiliate Clinical Research Site over the award period of performance) for support of two or more Affiliate Clinical Research Sites. No budget will be approved by the government exceeding **\$7.2M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

## Clinical Research Sites

- The period of performance is **4** years.
- The anticipated direct costs budgeted for the entire period of performance for a Clinical Research Site will not exceed **\$1.2M**. 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 **\$1.2M** in direct costs or using an indirect cost rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

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

For this award mechanism, direct **for the Coordinating Center** must be requested for:

- Travel costs for the PI and up to four additional members to present project information or disseminate project results at a PCRCP program meeting **each year** during the period of performance. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings

May be requested for (not all-inclusive):

- Salary support for personnel needed to meet the goals of the consortium, such as the PI, Supervising Clinical Research Coordinator, Administrative Assistant(s), Research Nurse(s), Statistician(s), Database Manager, and Informatics Manager
- Consortium-related meetings, teleconferences, and travel among participating investigators

- Database generation, software development, and website design
- Purchase of computers, specialized software, and specialized software licenses pertinent to Coordinating Center-specific responsibilities for use at participating institutions
- Costs related to establishing financial sustainability (e.g., fees for legal consultation)
- Other costs directly associated with planning and developing the consortium collaborations and resources
- Costs for up to two investigators to travel to two scientific/technical meetings per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the PCRCP Consortium Award Mechanism

Direct costs for **Clinical Research Sites** must be requested for:

- Costs for up to two investigators to travel to one or two scientific/technical meetings per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the PCRCP Consortium Award Mechanism

May be requested for (not all-inclusive):

- Salary support for personnel needed to meet the goals of the consortium such as the PI, Clinical Research Coordinator, Research Nurse, and Data/Informatics Coordinator
- Consortium-related meetings, teleconferences, and travel among participating institutions
- Computers and general software required to participate in the consortium
- Other costs directly associated with planning and developing the consortium

Cost sharing and utilization of other funding sources are encouraged.

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:

- **Coordinating Center (*to be reviewed in addition to the All Sites criteria below*):** All Coordinating Center applications will be evaluated according to the following criteria. Of these, Personnel, Consortium Components, and Study and Data Management are equally the most important, with the remaining criteria listed in decreasing order of importance.
  - **Personnel**
    - How well the PI or other key personnel have demonstrated appropriate expertise in prostate cancer and in the design and administration of multi-institutional prostate cancer clinical trials
    - Whether the PI and key personnel have previous success in acquiring funding for clinical trials
    - Whether the Supervising Clinical Research Coordinator, who will interact with all Clinical Research Coordinators, possesses the appropriate expertise to coordinate regulatory approvals, coordinate participant accrual, and coordinate study activities across sites
  - **Consortium Components**
    - Whether the application includes all required components to develop the Consortium Organizational Structure (e.g., Clinical Consortium Committee, Coordinating Center, and Clinical Research Sites, including Affiliate Clinical Research Sites)
    - How well the components as proposed will function as an integrated unit
    - To what degree the identified Affiliate Clinical Research Sites will be able to function in the consortium as demonstrated by prior multi-center clinical trial collaborations
    - Whether the identified Affiliate Clinical Research Sites have access to unique patient populations (high-risk, underserved, and/or military populations with prostate cancer) that will enhance patient diversity in consortium trials, and whether they have demonstrated prior success with recruiting the available patient populations for

clinical trials that will enable them to achieve the performance metrics outlined by the Coordinating Center

- **Study and Data Management**

- How the strategies for the development and implementation of data management and statistical plans will provide access to data, data security, and data integrity
- Whether there is an outline of an appropriate study management plan, including plans for ongoing communication, quality control, and quality assurance
- Whether there are appropriate plans for the development of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from consortium-sponsored studies
- Whether there are appropriate plans for rapid publication and other public dissemination of data generated by the consortium
- Whether all relevant privacy issues have been addressed appropriately

- **Financial Management**

- Whether the PI and/or other key personnel have appropriate experience and expertise in fiscal management of multi-institutional clinical research studies
- How well the Coordinating Center personnel demonstrate ability and commitment to achieving financial sustainability of the consortium by the end of the award period

- **Coordinating Center Two Initial Clinical Trials**

- **Personnel (applicable if a clinical trial(s) originates from outside the Coordinating Center and key personnel have not been previously listed)**
  - Whether the PI and other key personnel in the clinical trial have been named and whether they have the appropriate expertise in conducting and completing prostate cancer clinical trials
- **Study Design**
  - Whether the trials are focused on potentially high-impact, novel, therapeutic interventions
  - Whether the study population has been adequately described
  - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research in each trial
  - Whether the investigational drugs or devices have been adequately described

- Whether the proposed timelines indicate increased efficiency as a result of consortium participation
- **Regulatory Process**
  - Whether the trials will be ready for initiation at a time appropriate for implementation by the consortium
  - Whether there are appropriate plans for the coordination of IRB submissions and approvals at participating sites
  - Whether there is an appropriate plan for developing procedures to ensure compliance with FDA regulations for investigational agents
  - Whether the appropriate IND/IDE numbers have been provided
- **Impact**
  - Whether the trials address at least one of the [FY21 PCRP Overarching Challenges](#)
  - To what extent the intervention or device to be tested, if the study is successful, will have a significant impact on prostate cancer
- **All Sites (Clinical Research Sites and Coordinating Center):** All applications will be evaluated according to the following criteria, which are of equal importance.
  - **Personnel**
    - Whether the PI meets the eligibility requirements
    - How the research team’s background and expertise are appropriate with respect to its ability to perform multi-institutional prostate cancer clinical research
    - To what extent the research team has the ability and experience to contribute substantially to the design and conduct of consortium clinical trials
    - Whether the named institutional Clinical Research Coordinator has the appropriate experience in guiding clinical protocols through the regulatory approval processes and the ability to foster communication with other consortium Clinical Research Coordinators
    - Whether there are appropriate levels of effort for successful conduct of the proposed work
    - If applicable, whether the description of past performance of a previously received PCRP Clinical Consortium Award demonstrates successful achievement of previous award metrics and other substantive individual contributions to consortium activities; if past performance was directly affected by the COVID-19 pandemic and/or other significant event, how well the site describes plans to resolve or mitigate those issues

to increase performance for the new award

○ **Institutional Resources and Commitment**

- Whether the institution has demonstrated appropriate commitment to working with the consortium through the provision of facilities and resources
- How the PI is supported by the availability of and accessibility to facilities and resources, especially in regard to specimen collection and processing
- Whether the institution possesses appropriate resources and expertise for data management and maintaining security and confidentiality
- How well the applicant has demonstrated willingness and ability to resolve intellectual and material property issues with other institutions in the consortium
- Whether the institution has unique resources that may be of benefit to the consortium

○ **Participant Recruitment**

- Whether the PI has demonstrated sufficient access to the appropriate prostate cancer patient population(s) for consortium-sponsored studies
- Whether the PI has provided sufficient evidence of access to and ability to recruit patients from high-risk, underserved, and/or military populations
- Whether the institution has proven success in recruiting patients for clinical trials

○ **Collaborations**

- Whether the PI and other key members of the research team have demonstrated appropriate experience in collaborative prostate cancer clinical research
- How well the PI will integrate into the consortium and be a contributing member
- How well the PI's institution has facilitated the PI's collaborations

○ **Impact**

- To what extent the research team's areas of clinical research interest, if successfully developed, will support the presentation of clinical trials to evaluate high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer
- To what degree the anticipated outcomes from the institution's participation in the consortium, including the expected recruitment of patients from high-risk, underserved, and/or military populations to consortium-led studies, will impact consortium-led clinical trials and the [FY21 PCRP Overarching Challenges](#)

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 PCRPs, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Programmatic relevance to FY21 PCRPs 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 PCRPs 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 a Coordinating Center or Clinical Research Sites under the Clinical Consortium Award mechanism will not be allowed.

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.1.b. Pre-Award Meeting**

At the government's discretion, the PI and Clinical Study Coordinator or other personnel may be requested to participate in a pre-award meeting at the government's expense.

#### **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.

(Coordinating Center only): 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. It is the responsibility of the Coordinating Center to provide Inclusion Enrollment Reports for all trials funded under the FY21 Clinical Consortium Award.

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.
- 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 centimeters x 27.94 centimeters).
- 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.
- The application does not address at least one of the [FY21 Overarching Challenges](#).

- The PI does not meet the eligibility criteria.

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

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

### II.H.3. Application Submission Checklist

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

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

## APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CCA	Clinical Consortium Award
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
FDA	Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IDE	Investigational Device Exemption
IND	Investigational New Drug
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
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