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

Health Equity Research and Outcomes Improvement Consortium Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-PCRP-HEROICA

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), July 15, 2021

- **Application Submission Deadline:** 11:59 p.m. ET, July 29, 2021

- **End of Application Verification Period:** 5:00 p.m. ET, August 3, 2021

- **Peer Review:** September 2021

- **Programmatic Review: Stage 1:** December 2021

- **Invitation for Oral Presentation:** December 2021

- **Programmatic Review, Stage 2:** 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.B. Award Information

The FY21 PCRP Health Equity Research and Outcomes Improvement Consortium (HEROIC) Award supports a synergistic, multi-institutional collaboration incorporating innovative and translational approaches that have the potential to make a major impact on specific FY21 PCRP Overarching Challenges. Therefore, all applications are *required* to address one or both 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:

  o The mental and emotional health of patients and their families/caregivers

  o Impact of quality of life considerations on decision-making after diagnosis and/or treatment

  o Identification of vulnerable groups of men and their families at great risk of quality of life detriments

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

- **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.

Each application must outline and identify all key members of the consortium, which must include four to six Research Teams total; one Research Team will be led by a Consortium Director, and the remaining three to five Research Teams will be led by Research Team Principal Investigators (PIs). A minimum of three institutions must be represented. The consortium must include leading scientists and/or clinicians who have specific expertise related to prostate cancer, health disparities, and/or survivorship research or other areas of expertise related to addressing the overarching theme of the proposal. All consortia must include at least one prostate cancer consumer advocate that has an active role in every aspect of the proposed consortium's work.

Consortia funding will be offered in two phases. Phase 1 of the HEROIC Award will enable the consortium to lay the groundwork for the research effort, including the conduct of preliminary research projects to demonstrate proof of concept of the proposed central hypothesis. Phase 2 of the HEROIC Award will enable the execution of the full research effort, including multiple, parallel projects supported by the preliminary data generated in phase 1, which approach the research problem from a variety of perspectives. Phase 1 awardees will be eligible to compete for phase 2 funding in FY23 pending availability of funds. It is the program's intent that all phase 1 recipients will receive phase 2 funding pending successful achievement of phase 1 goals.

Phase 1 HEROIC Award: The first phase of funding is intended to provide the initial support necessary to establish the infrastructure of the consortium and conduct pilot studies that will generate preliminary data and demonstrate feasibility for achieving the aims of the completed project in phase 2. Key aspects of phase 1 HEROIC Award applications include the following:

- *Personnel:* The HEROIC Award mechanism requires a multi-PI partnership between one Consortium Director and three to five Research Team PIs. The Consortium Director will be responsible for the majority of the administrative tasks associated with application submission. All PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual submission requirements for the Consortium Director and Research Team PIs, refer to II.D.2.b.i Step 2: Full Application Guidelines

  The Consortium Director is expected to have experience in successfully leading the design, administration, and management of multi-institutional research projects. The Consortium Director should create an environment that facilitates the advancement of translational research efforts while also fostering and supporting innovation and creativity, with consistent, intensive interaction with the Research Teams in a way that engages all members of the consortium in all aspects of the research projects. Research Teams in this consortium should be comprised of scientists and/or clinicians who have made significant contributions to the field of prostate cancer or who have specific expertise related to health disparities or survivorship or other areas of expertise related to the research project. All team members should be integrally involved throughout the planning and implementation of the research project.

  This award encourages the establishment of new collaborations. If support for a pre-existing consortium is proposed, then it should be apparent why the Research Teams collectively represent the best group to address the proposed research question. Each Research Team is encouraged to consider including promising Early-Career Investigators (within 5 years of their last postdoctoral research position [Ph.D.], clinical fellowship [M.D.], or equivalent), scientists from nontraditional disciplines, and/or Epidemiologists/Public Health Experts, where appropriate, to enhance the consortium's efforts.

- *Consumer advocate involvement:* The consortium must include at least one prostate cancer consumer advocate. The consumer advocate(s) are expected to represent the perspective of the patient population(s) that are most relevant to the consortium's proposed research, and therefore should be from a recognized advocacy organization or have demonstrated prior contributions toward efforts to address prostate cancer issues in the populations of interest. The prostate cancer consumer advocate(s) must have an active role in every aspect of the proposed consortium's work, including consortium conception and design, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public. The consumer advocate(s) must be integrated into and play an active role in the leadership and decision-making committees for the consortium. Examples of appropriate integration include membership on advisory board(s) and steering committee(s), participation in project/aim teams, and attendance at all consortium-related meetings.

- *Infrastructure development:* Support must be utilized to develop key infrastructure elements necessary for successful conduct of collaborative, multi-institutional projects by the end of phase 1, including but not limited to:

- o Develop the infrastructure of the consortium (e.g., building appropriate collaborations, outlining an administrative and management plan, developing a research and communication plan, and devising an intellectual property plan) and a multi-institutional research team inclusive of scientists, clinicians, and prostate cancer consumer advocate(s).

- o Acquire research resources, patient cohorts, and/or datasets that will be needed for current or future consortium projects.

- o Develop a plan to disseminate information regarding the procurement and distribution of data and/or biospecimens to the non-consortium prostate cancer research community.

- o Prepare documents for obtaining approvals from local Institutional Review Boards (IRBs), as applicable.

- o Develop informed consent forms, as applicable.

- *Pilot projects:* Applications must outline and describe the pilot projects that will be conducted during the phase 1 award. Proposed pilot projects are intended to demonstrate proof of concept and provide preliminary data that will demonstrate the feasibility of achieving the aims that are planned for phase 2 funding. Additional pilot projects to explore innovative approaches to address the hypothesis may also be included. Preliminary data to support the feasibility of the research hypotheses and research approaches and/or the clinical relevance of the idea may be included, but are not required. *Clinical trials are not allowed.* Applicants must submit a statistical plan that includes a preliminary power analysis that reflects sample size projections that will answer the hypothesis and/or objectives of the proposed project (if applicable). It is expected that the research and statistical plan and power analysis will be updated based on the pilot study data for the FY23 phase 2 HEROIC Award application.

Note: An *invited* oral presentation is a requirement for review of phase 1 HEROIC Award applications at the programmatic review level, as described in Section II.D, Full Application Submission Content.

Phase 2 HEROIC Award: The following is an initial description of the scope and intent of the planned phase 2 HEROIC Award, which may be offered by the PCRP in FY23 to further support these research efforts. The information provided here is based on anticipated FY23 appropriations; funding opportunity details may need to be adjusted should program characteristics and/or requirements change (e.g., actual FY23 appropriation amount, congressional language). The following description of the scope and intent of the phase 2 award is provided at this time for transparency and to assist investigators in preparing applications for phase 1. Only the recipients of the FY21 PCRP phase 1 HEROIC Award will be eligible to compete for phase 2 funding. It is the program's intent that all phase 1 recipients will receive phase 2 funding pending successful achievement of phase 1 goals.

- *Funding amount:* The anticipated combined direct costs budgeted for an FY23 phase 2 HEROIC Award for the entire 4-year period of performance for the Consortium Director's and each Research Team PI's applications will not exceed $10M. Due to the annual

appropriations for this program, there is no guarantee that funds will be available in FY23 to implement phase 2 of this HEROIC Award.

- *Research project:* Phase 2 HEROIC Awards are expected to support research efforts including multiple, parallel projects that will build off of the preliminary data generated by the pilot projects from phase 1 and have the potential to make a major impact on advancing health equities, reducing disparities, and/or improving quality of life and overall health and wellness for those impacted by prostate cancer. Proposed research efforts in phase 2 should emphasize translational research approaches spanning preclinical to clinical studies, with a focus on efforts that will readily translate to direct patient benefit. Consortia are encouraged to include additional pilot projects that incorporate innovative approaches or ideas not included in the phase 1 pilot projects; phase 2 pilot projects are intended to generate new ideas integral to the central research hypothesis with clear potential for translation. Multidisciplinary approaches are strongly encouraged.

- *Personnel:* It is expected that the same research sites, investigators, and prostate cancer consumer advocate(s) named in the phase 1 HEROIC Award will be named in the phase 2 award. Any changes to key personnel should be fully justified.

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

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, the CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY21 PCRP priorities.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public. Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the

partners bring to the research effort, ultimately advancing cancer research that is of significance to the Warfighter, military families, and the American public.

The CDMRP intends that information, data, and research resources generated under awards funded by this program announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

The anticipated combined direct costs budgeted for the entire period of performance for an FY21 phase 1 HEROIC Award will not exceed **$2.70M**. 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 $12.96M to fund approximately three phase 1 HEROIC Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. *Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes*. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

If the proposed research is cooperative (i.e., involves more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical research is defined as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living

individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. *Note:* Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

For phase 1 HEROIC awards, clinical trials are not allowed. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Use of DOD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active-duty military patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

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

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis SC, et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature*, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

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

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

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. *Intramural Submission: 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) or higher are eligible to be named as a Consortium Director or Research Team PI on an application.

An investigator may be named as a Consortium Director on only one application.

There are no limits on the number of applications for which an investigator may be named as a Research Team PI for this HEROIC Award program announcement. Investigators are discouraged from being named on multiple applications unless they are clearly addressing distinct research questions.

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.

- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

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

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

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

II.D.1. Address to Request Application Package

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

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

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

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

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

in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

The Consortium Director must complete the pre-application submission process and submit the contact information for each Research Team PI. Each Research Team PI will then be notified of the pre-application submission separately by email. *Each Research Team PI must follow the link in the notification email in order to associate their full application package with that of the Consortium Director. After following the link, each Research Team PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.* If not previously registered, the Research Team PIs must register in eBRAP. A new pre-application based on this research project should not be initiated by the Research Team PIs. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Research Team PIs will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Research Team PI's required full application package components to eBRAP.

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 or 301-682-5507 to request a change in designation.

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

The applicant organization and associated PIs 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 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 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

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for W81XWH-21-PCRP-HEROICA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-21-PCRP-HEROICA from eBRAP (https://ebrap.org).

Extramural Submissions	Intramural DOD Submissions
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: - Attachments - Research & Related Personal Data - Research & Related Senior/Key Person Profile (Expanded) - Research & Related Budget - Project/Performance Site Location(s) Form - Research & Related Subaward Budget Attachment(s) Form - Additional Application Component(s)	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: - Attachments - Key Personnel - Budget - Performance Sites - Other **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.

Extramural Submissions	Intramural DOD Submissions
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. **Note:** 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 *prior to* the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period	
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 *with the exception of the Project Narrative and Research & Related Budget Form*.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PIs 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 *with the exception of the Project Narrative and Research & Related Budget Form*. 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.

Extramural Submissions	Intramural DOD Submissions
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

The CDMRP requires separate full application package submissions for the Consortium Director and each Research Team PI, even if the PIs are located within the same organization. Applications submitted by the Consortium Director and Research Team PIs must represent a minimum of three institutions. Consortium Director and Research Team PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. ***Note: All associated applications (Consortium Director and each Research Team PI) must be submitted by the full application submission deadline.***

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 (25-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the overall goals of the proposed consortium using the outline below.

– **Overarching Challenge:** State explicitly which of the two allowed FY21 PCRP Overarching Challenge(s) the proposed consortium will address. Describe how the collaborative research team will address the identified PCRP Overarching Challenge(s) in a way that will make a major impact for prostate cancer patients.

– **Central Hypothesis:** State the consortium's central hypothesis to be tested.

– **Objectives:** Briefly explain the consortium's objectives that will be addressed by the phase 1 and potential phase 2 projects led by the Consortium Director and Research Team PIs. Explain how the projects will support the consortium's central hypothesis.

Personnel Experience and Expertise in Multi-Institutional Collaboration and Consortium Development

– **Consortium Composition:** Describe how the consortium is composed of integrated Research Teams of leading investigators and one or more consumer advocates from appropriate disciplines and institutions. Explain how the consortium brings different disciplines together with one overarching plan to address the central hypothesis. While not required, identify any promising Early-Career Investigators (within 5 years of their last postdoctoral research position [Ph.D.], clinical fellowship [M.D.], or equivalent), scientists from nontraditional disciplines, and/or Epidemiologists/Public Health Experts that are included in the Research Teams and how they will enhance the consortium's efforts.

– **Consortium Director:** Describe the Consortium Director's previous experience and accomplishments as they relate to the design, administration, and management of multi-institutional prostate cancer research projects, with particular emphasis on experience in leading translational research efforts addressing prostate cancer health disparities, survivorship, and/or other areas related to addressing the overarching theme of the proposed research.

– **Consortium Infrastructure:** Explain how the Consortium Director will use the consortium infrastructure to support the advancement of translational research efforts within the consortium, while also supporting an environment that will foster innovation and creativity that will lead to new ideas integral to the central research hypothesis. Include plans for how the Consortium Director will use consistent, intensive interaction with the Research Teams in a way that engages all members of the consortium in all aspects of the research projects.

– **Consortium Organization:** Provide a description of the projected consortium organization. If support for a pre-existing consortium is proposed, then describe why the Research Teams collectively represent the best group to address the proposed research question must be apparent within the application. Research Teams must include scientists and/or clinicians who have made significant contributions to the field of prostate cancer in health disparities, survivorship, and/or other areas related to addressing the overarching theme of the proposed research. At least one Research Team must also include a prostate cancer consumer advocate. Describe the Research Teams, including their significant contributions to the field of prostate cancer in health disparities, survivorship, and/or other areas related to addressing the overarching theme of the proposed research. Describe the projected contributions and overall commitment of the Research Teams to developing a consortium to reduce health disparities, advance health equity, and/or improve quality of life and survivorship for all those impacted by prostate cancer. *Note:* Research Teams must represent a minimum of three institutions across the consortium. Describe the commitment to prostate cancer clinical research, which may include levels of effort, funding, and interactions with consumer advocacy groups.

– **Consumer Advocates:** Describe the integral roles that at least one or more consumer advocate(s) will play in the planning, design, implementation, and evaluation of the proposed research project. Identify the advocacy organization the consumer is affiliated with and/or describe the consumer advocate's prior contributions toward efforts to address prostate cancer issues in the populations of interest. The prostate cancer consumer advocate(s) should submit a letter of collaboration.

– **Administrative Management and Communication:** Describe the plans for administrative management, research, and communication that will support the development of the consortium. The plan should describe how the consortium will facilitate group interactions, adherence to regulatory requirements, administrative interactions, and oversight by advisory board(s) and/or steering committee(s). Include a description of how communication between and among consortium team members and their institutions will be accomplished and facilitate real time data sharing.

Phase 1 Pilot Projects

Consortia are required to conduct pilot projects that will demonstrate proof of concept of the central hypothesis and provide preliminary data that will demonstrate the feasibility of achieving the aims that are planned for phase 2 funding. The number of pilot projects proposed is under the discretion of the consortium, but it is expected that the preliminary data generated from phase 1 pilot studies will serve as the rationale and basis for the studies that will be proposed in a phase 2 HEROIC Award application in FY23, pending availability of funds. For each pilot project proposed, describe the project in detail using the outline below. Start each project on a separate page:

– **Title:** Provide a title for each project.

- **Project Team:** Identify the project leader (either the Consortium Director or one of the Research Team PIs) and any key personnel or contributions from other Research Teams, as appropriate.

- **Background:** Present the ideas and reasoning behind the proposed research. The application must provide a sound scientific rationale to support the proposed project and its feasibility as established through the demonstration of logical reasoning and a critical review and analysis of published literature; include relevant literature citations. While not required, include any preliminary data to support the feasibility of the research hypotheses and research approaches and/or the clinical relevance of the idea. Any unpublished, preliminary data provided should originate from the laboratory of the PIs or members of the research team. If applicable, describe how the proposed project represents an innovative approach to addressing the central hypothesis by proposing new paradigms, challenging existing paradigms, or otherwise being highly creative.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

- **Specific Aims:** Concisely explain the project's specific aims to be funded by the phase 1 application. The specific aims should be aligned with the specific aims/tasks outlined in the SOW.

- **Research Strategy and Feasibility:**

  - Describe the experimental design, methods, and analyses, including appropriate sample-size estimation and controls, in sufficient detail for scientific evaluation that will include an assessment of overall project feasibility. Include information describing the availability of required resources and how the Research Teams will maximize the use of the available resources and minimize unnecessary duplication of resources among consortium members, if applicable.

  - Address potential problem areas and present alternative methods and approaches.

  - If applicable, describe how the proposed project represents an innovative approach to addressing the central hypothesis by proposing new paradigms, challenging existing paradigms, or otherwise being highly creative.

  - If applicable, describe the statistical plan and preliminary power analysis to justify the number of research subjects or samples (animal or human) proposed. Describe how the power calculations will be sufficient to demonstrate proof of concept and provide preliminary data that will demonstrate the feasibility of achieving the aims that are planned for phase 2 funding. Describe the biostatistical expertise that will be available to support the analysis(es).

  - If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the clinical expertise available to support the project, if applicable. Provide

information to support the availability of and access to the appropriate resources, patient population(s), and/or samples. ***Phase 1 awards cannot be used to conduct clinical trials.***

- ▪ If applicable, describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the Food and Drug Administration (FDA).

- – **Proof of Concept:**

  - ▪ Describe the anticipated outcomes of the pilot projects. Explain how the data generated by the pilot projects will demonstrate proof of concept of the central hypothesis and feasibility of achieving the aims planned for a phase 2 HEROIC Award application to be submitted in FY23 (pending availability of funds).

- ○ **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.

  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

○ **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Describe the proposed consortium and pilot projects, including the following elements:

– **Background:** Present the ideas and reasoning behind the proposed effort.

– **Overarching Challenge:** State the FY21 PCRP Overarching Challenge(s) the proposed consortium will address. Describe how the collaborative research team will address the identified PCRP Overarching Challenge(s) in a way that will make a major impact for prostate cancer patients.

– **Central Hypothesis:** State the consortium's central hypothesis to be tested.

– **Pilot Projects and Objective:** Briefly explain the consortium's proposed pilot projects that will be conducted by the consortium. Explain the objective(s) to be reached by the pilot projects and how the projects will serve as the rationale and basis for the consortium's central hypothesis.

– **Impact:** Explain how the proposed consortium will make a major impact in addressing the identified FY21 PCRP Overarching Challenge(s) and ultimately provide progress toward 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.

○ **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

– Clearly describe, in a manner readily ***understood by readers without a background in science or medicine***, the rationale, objective, and aims of the application.

– Describe the ultimate applicability of the research.

▪ What are the likely contributions of this study to the FY21 PCRP Overarching Challenges?

- What types of patients will the consortium's efforts ultimately help and how will it help them?

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

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

○ **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** The suggested 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 HEROIC 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.

Each PI must submit an identical copy of a jointly created SOW. The contributions of the Consortium Director and each Research Team PI should be noted for each task.

○ **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Explain in detail how the proposed consortium's research goals, if successful, will make a major impact in addressing the identified FY21 PCRP Overarching Challenge(s). Describe the anticipated long-term gains from the proposed research and how they would make an impact on prostate cancer patient care and ultimately contribute to the goal of eliminating death from prostate cancer and enhancing the well-being of Service Members, Veterans, and all the men and their families who are experiencing the impact of the disease.

○ **Attachment 7: Inclusion of Women and Minorities (four-page limit): Upload as "Inclusion.pdf".** *(Attachment 7 is only applicable and required for applications that propose clinical research.)* Describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. The suggested Inclusion Enrollment Report format, Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

○ **Attachment 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 (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

    - ○ PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

        - – For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

        - – For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- ○ Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf".

  - – Include biographical sketches for collaborators at each Research Site.

  - – Include biographical sketch(es) for consumer advocate(s).

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

  - – Include current/pending support for the collaborators at each Research Site.

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.

Consortium Director and Research Team PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Consortium Director should not include budget information for Research Team PIs, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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.

Suggested DOD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Research Team PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete a separate military budget using "Suggested Collaborating DOD Military Facility Budget Format" (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]) (Attachment 9) to show all direct and indirect costs. 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.

Application Components for each Research Team PI

Each Research Team PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Consortium Director.

For each Research Team PI, the Consortium Director must identify whether each Research Team PI will be named on an extramural or intramural application (in accordance with the guidelines in Section II.C.1.a, Organization) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). Each Research Team PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for each Research Team PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

  ○ **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Consortium Director and each Research Team PI should be noted for each task.

  ○ **Attachment 8: Representations (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

  ○ **Attachment 9: Suggested Collaborating DOD Military Facility Budget Format: Upload as "MFBudget.pdf".** Refer to the General Application Instructions,

Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

○ PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

○ 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, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

Consortium Director and Research Team PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for each Research Team PI should not include budget information for the Consortium Director, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form:

  ○ **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.)

  ○ **Intramural DOD Collaborator(s):** Complete a separate DOD military budget, using the "Suggested Collaborating DOD Military Facility Budget Format" (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]), and upload to Grants.gov attachment form as Attachment 9. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

Additional Application Components

In addition to the complete application package, phase 1 HEROIC Award applications also require the following components:

- **Oral Presentation:** PIs named in phase 1 applications that are selected for final consideration in Stage 2 of Programmatic Review will be required to give an oral presentation (see Section II.E.1.b, Programmatic Review) that will be held virtually in January 2022. *Consortium Director and Research Team PIs will attend and give the oral presentation*.

  Each presentation will include a 20-minute talk by the PIs, followed by a 30-minute question-and-answer session with Programmatic Panel members. The following questions will be the topics for discussion during the PIs' talk and the question-and-answer session. PIs who are invited must prepare a presentation consisting of no more than five slides that specifically address these questions:

  ○ Without addressing your specific project(s), what do you consider the most critical barriers to overcome in the clinical management of prostate cancer within the context of the FY21 PCRP Overarching Challenges(s) you selected/identified?

  ○ Without addressing the specific technical/scientific aspects of your project, how do you envision transitioning the results from your proposed research (both phase 1 and plans for phase 2) into a direct benefit for individuals with, or at risk of, prostate cancer?

  ○ Without addressing the specific technical/scientific aspects of your project, what leadership skills will be used in the consortium's effort and beyond to create an

environment that fosters creativity and helps translate results that will make a major impact on prostate cancer patient care?

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 PIs will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

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

II.D.5. Funding Restrictions

The maximum period of performance is **2** years for a phase 1 award.

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

The anticipated combined direct costs budgeted for the entire period of performance for the Consortium Director's and each Research Team PI's applications will not exceed **$2.70M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the government will not exceed **$2.70M** or use an indirect cost rate exceeding each organization's negotiated rate.

A separate award will be made to each PI's organization. The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

For this award mechanism, direct costs must be requested for:

- Travel costs for each PI to attend a 1-day meeting held in the National Capital Area once during the award period of performance. This meeting will be held to provide a presentation on progress at a CDMRP PCRP Meeting. ***Travel costs for each PI should be requested on their individual budget.*** These travel costs are in addition to those allowed for annual scientific/technical meetings

May be requested for (not all-inclusive):

- Consortium-related meetings, teleconferences, and travel among participating investigators

- Other costs directly associated with planning and developing the consortium collaborations and resources

- Costs for two investigators to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the PCRP HEROIC Award

Must not be requested for:

- Clinical trial costs

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**, which are of equal importance:

- **Impact**
  - To what degree the proposed consortium's research goals, if successful, will make a major impact in addressing the identified <u>FY21 PCRP Overarching Challenge(s)</u>

- To what degree the anticipated long-term gains from the proposed research would make an impact on prostate cancer patient care, and ultimately contribute to the goal of eliminating death from prostate cancer and enhancing the well-being of Service Members, Veterans, and all the men and their families who are experiencing the impact of the disease

- **Consortium Structure**

  - Whether the identified Consortium Director and Research Teams represent an integrated team of leading investigators from different disciplines and institutions to support one overarching plan to address the central hypothesis

  - How well the Consortium Director will use the consortium infrastructure to support the advancement of translational research efforts, while also supporting an environment that will foster innovation and creativity that will lead to new ideas integral to the central research hypothesis

  - How well the Consortium Director has outlined plans that facilitate consistent, intensive interaction with the Research Teams in a way that engages all members of the consortium in all aspects of the research projects

  - To what degree the consumer advocate(s) will play an integral role in the planning, design, implementation, and evaluation of the proposed research project

  - How well the infrastructure includes building appropriate collaborations, outlining plans for administrative management, research, and communication, and devising an intellectual and material property plan

  - To what degree the inclusion of Early-Career Investigator(s), scientists from nontraditional disciplines, and/or Epidemiologist/Public Health Experts will enhance the consortium's efforts, if applicable

  - How well the Research Sites will maximize the use of resources and minimize unnecessary duplication of resources, if applicable

  - Whether the consortium includes a plan for dissemination of information to the non-Consortium prostate cancer research community

- **Personnel**

  - How well the Consortium Director's qualifications and experience demonstrate appropriate expertise in the design, administration, and management of multi-institutional research projects

  - How well the Consortium Director's experience demonstrates appropriate expertise in leading translational research efforts addressing prostate cancer health disparities, survivorship, and/or other areas related to addressing the overarching theme of the proposed research

- Whether the Research Teams include scientists and/or clinicians who have made significant contributions to the field of prostate cancer in health disparities, survivorship, and/or other areas related to addressing the overarching theme of the proposed research

- How the consortium team's background and expertise are appropriate for accomplishing the proposed research and the FY21 PCRP Overarching Challenge(s) that will be addressed

- How well the consortium participants are committed to developing a consortium to reduce health disparities, advance health equity, and/or improve quality of life and survivorship for all those impacted by prostate cancer

- How well the consumer advocate(s) is/are integrally involved in the research and management processes, with appropriate qualifications and background

- How appropriate the levels of effort are for successful conduct of the proposed work

- **Research Strategy & Feasibility**

  - How well the scientific rationale supports the research and its feasibility, as demonstrated by logical reasoning and a critical review and analysis of the published literature

  - If applicable, how well the preliminary data supports the feasibility of the research hypotheses and research approaches and/or the clinical relevance of the idea

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

  - Whether any of the proposed projects represent innovative approaches to addressing the central hypothesis by proposing new paradigms, challenging existing paradigms, or otherwise being highly creative (if applicable)

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

  - Whether the statistical plan and preliminary power analysis are adequate for the study (if applicable)

  - Whether the power calculations will be sufficient to demonstrate proof of concept and provide preliminary data that will demonstrate feasibility of achieving the aims that are planned for phase 2 funding (if applicable)

  - Whether the application provides sufficient evidence to support the availability of and access to the resources, patient populations, and/or samples required for the study and whether the plan for the recruitment of subjects or the acquisition of samples is sufficient for the proposed research project (if applicable)

- ○ Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research (if applicable)

- ○ If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA

- ○ To what degree the proposed pilot projects, if successful, will provide sufficient data to demonstrate proof of concept of the central hypothesis and feasibility of achieving the aims planned for a phase 2 HEROIC Award application (pending availability of funds)

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

- **Budget**

  - ○ Whether the **direct** costs exceed the allowable direct costs as published in the program announcement

  - ○ Whether the budget is appropriate for the proposed research

- **Environment**

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

  - ○ Whether there is evidence for appropriate institutional commitment from each participating institution

- **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 PCRP, as evidenced by the following:

  Stage 1: During the first stage of programmatic review, applications will be selected for Stage 2 using the following equally considered criteria:

  - ○ Adherence to the intent of the award mechanism

  - ○ Program portfolio composition

○ Programmatic relevance to FY21 PCRP Overarching Challenges

○ Relative impact

Stage 2 (Oral Presentation): During the second stage of programmatic review, the following criteria will be used:

○ Understanding of barriers to overcome in the FY21 PCRP Overarching Challenge(s) selected/identified

○ Articulation of a realistic vision for transitioning the results of the project into a direct benefit for individuals with, or at risk for, prostate cancer

○ Capability to lead efforts that foster creativity and help translate results that will make a major impact on prostate cancer patient care

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 PCRP will be provided to the PIs 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

An organizational transfer of an award supporting the Consortium Director or Research Team PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

Refer to full text of the latest DoD R&D General Terms and Conditions; the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions; and the USAMRAA General Research Terms and Conditions with For-Profit Organizations for further information.

II.F.3. Reporting

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

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

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

Inclusion Enrollment Reporting Requirement *(only required for clinical research studies)*: Enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the

"Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

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

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

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

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.

- More than one application is received naming the same investigator as Consortium Director. Only the first application received will be accepted; additional applications will be administratively rejected.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An 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.

- A clinical trial is proposed.

- The application does not address at least one of the required FY21 Overarching Challenges.

- The PI does not meet the eligibility criteria.

- Application fails to name at least one prostate cancer consumer advocate.

- An application for which the proposed Consortium does not include one Consortium Director and three to five additional Research Team PIs.

- An application that does not represent a minimum of three institutions.

- Failure to submit all associated (Consortium Director and Research Team PI) applications by the deadline.

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	Consortium Director Completed	Research Team PIs Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"		
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"		
	Inclusion of Women and Minorities: Upload as Attachment 7 with file name "Inclusion.pdf" if applicable.		
	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		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		

Application Components	Action	Consortium Director Completed	Research Team PIs Completed
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget **(intramural submissions only)**	Complete the Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	Complete form as instructed		
Additional Application Components	**Action**	**Consortium Director Completed**	**Research Team PIs Completed**
Oral Presentation	Confirm ability to give an oral presentation virtually that is tentatively scheduled for January 2022 (if selected for Stage 2)		

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
HEROIC	Health Equity Research and Outcomes Improvement Consortium
HEROICA	Health Equity Research and Outcomes Improvement Consortium Award
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
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 Award
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