I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Dr. Barbara Terry-Koroma[1]

Health Disparity Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-18-PCRP-HDRA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 20, 2018

- **Application Submission Deadline:** 11:59 p.m. ET, October 11, 2018

- **End of Application Verification Period:** 5:00 p.m. ET, Ocotber 15, 2018

- **Peer Review:** December 2018

- **Programmatic Review:** February 2019

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

This Program Announcement must be read in conjunction with the General Application Instructions, version 20180329. The General Applications 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

New for 2018: **Application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their application Workspace package.**

II.A. Program Description

Applications to the Fiscal Year 2018 (FY18) 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 FY17 totaled $1.62 billion. The FY18 appropriation is $100 million (M).

The PCRP seeks to promote: highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; the next generation of prostate cancer investigators through mentored research; and resources that will facilitate translational research.

II.A.1. FY18 PCRP Overarching Challenges

The mission of the FY18 PCRP is to fund research that will lead to the elimination of death from prostate cancer and enhance the well-being of Service members, Veterans, and all men experiencing the impact of the disease. Within this context, the PCRP is interested in supporting research that addresses specific gaps in prostate cancer research and clinical care. Therefore, applications are *required* to address one or more of the following FY18 PCRP Overarching Challenges:

- Develop treatments that improve outcomes for men with lethal prostate cancer

- Reduce lethal prostate cancer in African Americans, Veterans, and other high-risk populations

- Define the biology of lethal prostate cancer to reduce death

- Improve the quality of life for survivors of prostate cancer

II.A.2. Award History

The PCRP Health Disparity Research Award mechanism was first offered in FY01. Since then, 544 Health Disparity Research Award applications have been received, and 96 have been recommended for funding.

II.B. Award Information

The Health Disparity Research Award supports promising research ideas that have high potential to make a significant impact in eliminating disparities in prostate cancer incidence, morbidity, mortality, and survivorship. The PCRP is interested in research that addresses all different aspects that contribute to health disparity in prostate cancer, including, but not limited to, social, cultural, and/or biological contributors. Proposed research ideas should be innovative, but primary emphasis will be placed on the potential impact of the proposed work.

The key components of this award mechanism are:

- **Impact:** Research supported by the Health Disparity Research Award will have the potential to make a significant impact in addressing prostate cancer health disparities. It is expected that the results of the study will improve the understanding of and/or address factors that contribute to differences in the disease experience across populations. The potential impact of the proposed research may be short-term or long-term, but it must be significant and progress beyond an incremental advance. It is the responsibility of the Principal Investigator (PI) to clearly and explicitly describe the potential impact of the proposed study to an area of prostate cancer health disparity and to convey its level of significance. Applications must include a detailed transition plan that articulates the pathway to moving the project's findings to the next phase of development after successful completion of the award, and continue advancing the research toward making a clinical impact, even if clinical impact is not an immediate outcome.

- **Innovation:** Applications are expected to include an innovative approach to addressing prostate cancer health disparities. Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other highly creative qualities. Research that is an incremental advance upon published data is not considered innovative. Multidisciplinary projects are especially encouraged. The inclusion of preliminary data is encouraged but not required. Any preliminary, unpublished data provided should be from the PI or a member(s) of the research team.

- **Research Scope:** Proposed projects may include basic, translational, or clinical research, including clinical trials. Investigators from a spectrum of disciplines, including but not limited to, basic science, engineering, bioinformatics, population science, psycho-oncology, translational research, and clinical research, are encouraged to submit applications, provided they are appropriately focused on an issue of prostate cancer health disparity. Only small-scale (i.e., up to and including Phase II or equivalent) clinical trials are allowed. Investigators proposing a clinical trial are highly encouraged to consider leveraging the PCRP Prostate Cancer Clinical Trials Consortium (PCCTC) (http://pcctc.org/) to facilitate

the rapid initiation and completion of the trial. Projects that incorporate population science-based approaches are particularly encouraged.

To maximize the potential for impact, investigators are strongly encouraged to incorporate the following components into their study design where appropriate: authentication of proposed cell lines; statistical rigor of preclinical animal experiments; incorporation of experiments to assess clinical relevance and translatability of findings. As such, the PCRP-funded Prostate Cancer Biorepository Network (PCBN) (http://www.prostatebiorepository.org) and/or the North Carolina – Louisiana Prostate Cancer Project (PCaP) (https://pcap.bioinf.unc.edu) are important resources to consider if retrospectively collected human anatomical substances or correlated data are critical to the proposed studies. Studies utilizing data derived from large patient studies that include long-term health records, biospecimen repositories, and pre-existing research that apply state-of-the-art genomic and/or proteomic analysis, bioinformatics, and/or mathematical models to such data are also encouraged.

New Investigator category: This award encourages research ideas from investigators in the early stages of their careers. The New Investigator category is designed to allow applications naming PIs who are ***early in their faculty appointments or in the process of developing independent research careers*** to compete for funding separately from established investigators. Applications naming PIs using the New Investigator category are required to include a collaborator (or collaborators) appropriate to the application who has experience in prostate cancer health disparity research, as demonstrated by a record of funding and publications. The application must describe the potential of the collaboration(s) to be successful and how the collaboration(s) will augment the PI's expertise to better address the research question. All applicants for the New Investigator category must meet specific eligibility criteria, as described in Section II.C, Eligibility Information.

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

The anticipated direct costs budgeted for the entire period of performance for an FY18 PCRP Health Disparity Research Award will not exceed **$600,000** for an award under the New Investigator category or **$1M** for an award under the Established Investigator category. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). 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.

Extramural Organizations: An assistance agreement (grant or cooperative 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. 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 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.

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 Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. *Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes*. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource 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.

A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

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 resources or databases, the application must describe the access at the time of submission and a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including 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. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should 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.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC 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. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled, "Research Involving Animals." ***Allow at least 2 to 3 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, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 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.

Health Disparity Research Resources: Potential applicants for this award are encouraged to seek collaborations and access to appropriate study populations through the following resources:

- Congressionally Directed Medical Research Programs: Search the CDMRP awards database at http://cdmrp.army.mil.

- The North Carolina – Louisiana Prostate Cancer Project: The PCaP was supported by the PCRP to conduct prostate cancer health disparity studies and developed a large biorepository of health disparity-related epidemiological data and biospecimens that may be requested for use by the research community. Information on PCaP investigators, data, and specimens is available at https://pcap.bioinf.unc.edu.

- The Prostate Cancer Biorepository Network: The PCBN is supported by the PCRP to develop and maintain a multi-institutional prostate cancer biorepository that facilitates the collection, processing, annotation, storage, and distribution of high-quality human prostate cancer biospecimens to be distributed to the prostate cancer research community. The PCBN offers several types of biospecimens that may be useful for health disparity studies. Information on these biospecimens is available at http://www.prostatebiorepository.org.

- National Cancer Institute Center to Reduce Cancer Health Disparities (CRCHD): Search for health disparity research and researchers at http://crchd.cancer.gov/index.html.

- National Institute on Minority Health and Health Disparities (NIMHD) Community Based Participatory Research (CBPR) Initiative: Contact the NIMHD at https://www.nimhd.nih.gov/programs/extramural/community-based-participatory.html for information on current CBPR programs and scientists and communities engaged in health disparity research.

- Uniformed Services University of the Health Sciences (USUHS) Center for Health Disparities: Search for programs and communities engaged in health disparity research at https://www.usuhs.edu/chd.

- American Association for Cancer Research, Minorities in Cancer Research (AACR MICR): Search for health disparity research and researchers at http://www.aacr.org/Membership/Pages/Constituency%20Groups/minorities-in-cancer-research___1C81B8.aspx.

- Cancer Prevention and Control Research Network (CPCRN): Contact the CPCRN at http://cpcrn.org/ for information on community participatory research to reduce cancer in disproportionately affected populations.

- Health Resources and Services Administration (HSRA) Office of Minority Health: Search for health disparity programs and funded investigators at https://www.hrsa.gov/index.html.

- National Institutes of Health (NIH) Research Portfolio Online Reporting Tool (NIH RePORTER): Search for NIH awards at http://projectreporter.nih.gov/reporter.cfm.

- Defense Technical Information Center (DTIC): Search for DoD and other Government-funded investigators through DTIC Technical Reports at http://www.dtic.mil/dtic/.

- National Library of Medicine, NIH, PubMed: Search for investigators publishing studies on prostate cancer health disparities at http://www.ncbi.nlm.nih.gov/pubmed.

- U.S. Department of Education: Search for institutions that may have increased access to disproportionately affected populations at http://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst.html.

- International Cancer Research Partnership: Search for investigators and studies relevant to health disparity that are supported by cancer research funders from several countries including the United States, European Union, United Kingdom, and Canada at https://www.icrpartnership.org.

- National Coalition for LGBT Health: For more information on programs focused on lesbian, gay, bisexual, and transgendered (LBGT) research, policy, education, and training, search http://www.healthlgbt.org.

- National LGBT Cancer Network: To obtain more information, search http://www.cancer-network.org.

In addition, applicants are encouraged to interact with organizations, as applicable to their proposed studies, such as the American Indian Health Care Association, National African American Outreach Program of the Patient Advocate Foundation, National Alliance for Hispanic Health, National Medical Association, National Rural Health Association, Prostate Health Education Network, and international organizations such as the African-Caribbean Cancer Consortium, African Organization for Research and Training in Cancer (AORTIC), Global Prostate Cancer Alliance, Malecare, Men of African Descent and Carcinoma of the Prostate (MADCAP) Consortium, Prostate Cancer Transatlantic Consortium, The Prostate Net, and the Urban League.

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 to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2019. For additional information refer to Section II.F.1, Federal Award Notices.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including 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, Government, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural DoD organization or from an extramural Federal organization may be submitted through a research foundation.

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

II.C.1.b. Principal Investigator

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

- **Established Investigator**

  The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent).

- **New Investigator**

  By the application submission deadline, the PI must have:

  ○ The freedom to pursue independent research goals without formal mentorship;

  ○ Not previously received a PCRP Health Disparity Research Award and/or Idea Development Award;

  ○ The PI must be an independent, early-career investigator within 10 years after completion of his/her terminal degree by the time of the application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.

  ○ New Investigators working under another investigator are eligible to apply for this award provided they can demonstrate that they have the freedom to pursue independent research goals without formal mentorship. Graduate students and junior postdoctoral fellows (i.e., fellows with less than 3 years of postdoctoral training by the application submission deadline) are not eligible to apply as a New Investigator.

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 http://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.

Each investigator may be named on only one FY18 PCRP Health Disparity Research Award application as PI.

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 is defined as an application submitted by an organization to Grants.gov.

Intramural DoD Submission is defined as an application submitted by a DoD organization to eBRAP.

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.

Extramural Submissions: 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 Submissions: Pre-application content and forms and full application packages must be accessed and submitted at eBRAP.org.

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*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through a Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

For Both Extramural and Intramural Applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. 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. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, each submission is assigned a unique log number by eBRAP. 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 PI 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.

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

- Health Disparity Research Award – *New Investigator*; or

- Health Disparity Research Award – *Established Investigator*

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. Note that the codes have recently been revised. 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 (R&R) 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 (R&R) 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 PIs 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.

   FY18 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.

   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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

   List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

   ○ **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. If the proposed research includes a clinical trial, briefly state the clinical intervention, subject populations(s), and phase of the clinical trial. 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.

- ○ **Biospecimen Resource Statement (one page-limit):** Provide a brief statement regarding whether the proposed research will require the use of prostate cancer biospecimens, and if so, whether the resources available through the PCRP-funded PCBN (http://www.prostatebiorepository.org) were considered as a source of samples for the proposed study.

- ○ *For New Investigators only:* Provide a biographical sketch for the PI (five-page limit). The PI's biographical sketch will be reviewed administratively to confirm eligibility but will not be included in the merit-based pre-application screening. Append the Eligibility Statement (one-page limit) to the biographical sketch using the Eligibility Statement template (available for download on the Full Announcement page under this funding opportunity in Grants.gov and on the Funding Opportunities & Forms page in eBRAP), signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met at the application submission deadline.

- **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 (http://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 the 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.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-18-PCRP-HDRA from Grants.gov (http://www.grants.gov) and create a Grants.gov Workspace. The 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-18-PCRP-HDRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 (R&R) 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 • R&R Subaward Budget Attachment(s) Form (if applicable)	**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 **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.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to the 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	**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.

Extramural Submissions	Intramural DoD Submissions
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.	
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.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, *with the exception of the Project Narrative and Budget Form,* may be modified. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Further Information	
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.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Budget cannot be changed after the application submission deadline.* Prior to the full application deadline, a corrected or modified full application package may be submitted. 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.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

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 (R&R) 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 (12-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Describe the proposed project in detail using the outline below.

    – **Background:** Present the ideas and reasoning behind the proposed research; explain how the proposed project addresses an area of health disparity in prostate cancer. Cite the relevant literature. Describe previous experience most pertinent to this application. While not required, include any preliminary data to support the scientific rationale.

    – **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis.

- **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.

- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls and endpoints to be tested (if applicable), in sufficient detail for scientific review.

  - Explain how this research strategy will meet the research goals and milestones. Address potential pitfalls and problem areas and present alternative methods and approaches.

  - Clearly identify the source of any proposed cell lines, and whether they were recently authenticated and/or tested for mycoplasma contamination, if applicable.

  - If the methodology is new or unusual, provide sufficient details for evaluation.

  - Describe the availability of the necessary resources, including human subjects or human anatomical samples; include a detailed plan for the recruitment of subjects or the acquisition of samples. Address any potential ethical concerns. Outline how approvals from local IRBs will be obtained and how the informed consent process will be initiated, as applicable.

  - Describe the statistical plan, including power analysis that reflects sample size projections that will address the hypothesis and/or the objectives of the project. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines (http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf).

- If the study does not include a clinical trial, describe how the clinical relevance of the anticipated findings will be determined, and whether the results will be validated in the appropriate patient cohorts, if applicable.

- **Clinical Trial (if applicable):** *Only small-scale (i.e., up to and including Phase II or equivalent) clinical trials are allowed.* Provide detailed plans for initiating the clinical trial within the first year and conducting the clinical trial during the course of this award. As appropriate, outline a plan for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other U.S. Food and Drug Administration [FDA] approvals). Describe the rationale for the trial and summarize the previous work that led to the development of the proposed clinical trial. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

  - Identify the intervention to be tested and describe the projected outcomes.

  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.

- Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the inclusion and exclusion criteria, the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects for the clinical trial.

- Describe any ethical issues (e.g., informed consent, information privacy, assessment of risk versus benefit of participation) raised by the proposed study, and provide a detailed plan for how the ethical issues will be addressed.

- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

- Describe the statistical model and data analysis plan with respect to the study objectives. Specify the number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

- Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, statistician) possesses the appropriate expertise in conducting clinical trial.

  – **Research Team:** Discuss the qualifications of the research team, each individual's specific contributions to the project, including how the appropriate expertise is incorporated to address the research question and enable the success of the proposed project. If prospective clinical studies are included, the PI or research team must demonstrate appropriate expertise in conducting clinical studies.

    - *For New Investigators only:* Name the required collaborator and describe how he or she will support the PI and project.

  ○ **Attachment 2: Supporting Documentation:** Combine and upload as a single file named "Support.pdf." Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

    There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

–   References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

–   List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

–   Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether 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 publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

–   Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

–   Letters of Support from Population- or Community-Based Organizations (if applicable): In cases where the PI is affiliated with a designated population- or community-based organization (see Section I.B, Award Information), inclusion of a letter of support from each organization is encouraged. Such letter(s) of support should explain the nature of the PI's relationship to the organization, the involvement of the PI with the affected population or community, the importance of the project within the affected population or community, any long-term application of the project to the affected population or community, and the PI's commitment to the affected population or community and health disparity.

–   Letters of Collaboration (*required* for New Investigators; *optional* for Established Investigators): Provide a signed letter from each collaborating individual or organization that describes the potential for the collaboration(s) to be successful, and how the collaborator(s) will support the project, to include unique expertise and/or availability of and access to research resources. 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.

- **For New Investigators,** if the PI is likely to change organizations during the award period of performance, (e.g., New Investigators transitioning into their first independent faculty position), describe how proposed collaborations will be maintained.

  – 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.

  – 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 patient 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 ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

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

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

Describe the proposed research project, including the following elements:

  – Background: Present the ideas and reasoning behind the proposed project.

  – Hypothesis/Objective: State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis.

- – Specific Aims: State the specific aims of the study.

- – Study Design: Briefly describe the study design, including appropriate controls.

- – Impact: Describe the impact of the proposed project on improving understanding of, and ultimately contributing to the reduction or elimination of disparities in, prostate cancer incidence, morbidity, mortality, and survivorship.

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

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

   - – Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.

   - – Describe the ultimate applicability of the research.

      - ▪ What types of patients will it help, and how will it help them?

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

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

      - ▪ If the research is too basic for near-term clinical applicability, describe the interim outcomes.

      - ▪ What are the likely contributions of this study to advancing the field of prostate cancer health disparity research?

○ **Attachment 5: Statement of Work (SOW) (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). For the Health Disparity Research Award mechanism, use the SOW format example titled, "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching.

   The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/ subaward site.

- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- Identify cell line(s) and commercial or organizational source(s) to be used.

- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND and IDE applications) by the FDA or other Government agency.

- Briefly state the methods to be used.

○ **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf."

Explain in detail how the project will have an impact on the reduction or elimination of the disproportionate effects of prostate cancer on the targeted population(s).

- *Describe the short-term impact:* Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research, including any clinically relevant results.

- *Describe the long-term impact:* Explain the anticipated long-term gains from the proposed research, including how the new understanding may contribute to the goal of understanding and ultimately eliminating disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship in the targeted population(s).

- *PCRP Overarching Challenges:* Summarize how the proposed project addresses and will help provide a solution to one or more of the FY18 PCRP Overarching Challenges.

○ **Attachment 7: Innovation Statement (one-page limit):** Upload as "Innovation.pdf."

Describe in detail how the proposed work is innovative. Research that represents an incremental advancement on published data is not considered innovative.

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

- Study concept: Investigation of a novel idea and/or research question.

- – Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.

  - – Novel method or technology: Development of a novel method or technology for prevention, detection, diagnosis, or treatment.

  - – Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- ○ **Attachment 8: Transition Plan (two-page limit):** Upload as "Transition.pdf." Provide information on potential methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award. The transition plan should include the components listed below.

  - – A description of the scientific or technical requirements needed to advance the research findings.

  - – An assessment of the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the study results into clinical practice.

  - – A timeline with defined milestones and deliverables describing the expected post-award progress of the results toward clinical impact.

  - – Details of the funding strategy that will be used to bring the outcomes to the next phase of development (e.g., specific potential industry partners; specific funding opportunities to apply for).

  - – A description of collaborations and other resources that will be used to provide continuity of development.

  - – A plan to distribute the findings or intervention to the prostate cancer community.

- ○ **Attachment 9:** *(Only applicable and required for applications submitted under the New Investigator category):* **Statement of Independence (one-page limit):** Upload as "Independence.pdf."

  For investigators not yet in an independent faculty position, complete and sign the Statement of Independence template (available for download on the Full Announcement page under this funding opportunity on Grants.gov and the Funding Opportunities & Forms page in eBRAP). The Statement of Independence must also be signed by the investigator's current mentor/supervisor.

- ○ **Attachment 10: Representations, if applicable (extramural submissions only):** Upload as "MandatoryReps.pdf." All extramural applicants must complete and submit the Required Representations template available on eBRAP

(https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- ○ **Attachment 11: DoD Military Budget Form(s), 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 the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page [(https://ebrap.org/eBRAP/public/ Program.htm)](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 and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 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, or mathematics 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.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

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

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

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

    - – Include biographical sketches for the required collaborator, if applying under the *New Investigator* category.

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

    – Include previous/current/pending support for the required collaborator, if applying under the *New Investigator* category.

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

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

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only**

    R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

    – **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, 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 DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 11. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

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

Applicant organizations and all subrecipient 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's 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.

New Requirement: In March 2018, the General Services Administration (GSA) implemented fraud prevention security measures in the SAM that require every *new* contractor registrant to provide a written (hard copy), notarized letter confirming the entity's Administrator authorized to register the entity in the SAM database or to make changes to its registration. Effective April 29, 2018, the notarized letter process is now mandatory on all *current* registrants at SAM who have a requirement to update data on their SAM record. The notarized letter is mandatory and is required before the GSA Federal Service Desk (FSD) will activate the entity's registration. The Office of the Secretary of Defense and GSA realize the length of time needed to transmit, receive, process, and approve the notarized letters presents a significant impact on the ability of the contracting activity to make timely awards, but these steps must be taken to mitigate fraud concern. ***Notarized letters are required for all new and existing SAM-registered entities.*** The notarized letters must be postal service mailed (not emailed or faxed) to the "Federal Service Desk" and must contain the information outlined in the SAM-posted Frequently Asked Questions (FAQs) at https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update. Instructions for domestic entities and instructions for international entities with embedded templates for use are also provided within the SAM Update notice with frequently asked questions at https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update.

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

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 retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. 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 Budget Form cannot be changed after the application submission deadline.

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

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) 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 prior to the application verification deadline.

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

II.D.5. Funding Restrictions

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

New Investigator category: The anticipated direct costs budgeted for the entire period of performance will not exceed **$600,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$600,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Eastablished Investigator category: The anticipated direct costs budgeted for the entire period of performance will not exceed **$1M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$1M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

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

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

- Salary

- Research supplies

- Equipment

- Research-related subject costs

- Clinical research costs

- Support for multidisciplinary collaborations, including travel

- Travel costs for one investigator to travel to one scientific/technical meeting per year to present project outcomes from the PCRP Health Disparity Research Award. ***The Government reserves the right to direct the selection of this meeting, should a PCRP-sponsored IMPaCT (Innovative Minds in Prostate Cancer Today) meeting be convened during the award period of performance.***

Awards made to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). 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 fund 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.4, 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.4***.

The CDMRP expects to allot approximately $11.8M of the $100M FY18 PCRP appropriation to fund approximately four New Investigator category and five Established Investigator category Health Disparity Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

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. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this funding opportunity will be funded with FY18 funds, which will expire for use on September 30, 2024.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following scored criteria. Of these criteria, Impact is the most important, with the remaining criteria listed in decreasing order of importance.

- **Impact**

  - How well the proposed research addresses an issue of health disparity in prostate cancer in the affected population or community.

  - To what extent the project could, whether in the short term or long term, lead to a significant reduction or elimination of disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship.

  - To what degree the expected results of the project will address and provide a solution to one or more of the PCRP Overarching Challenges.

- **Innovation**

  - To what degree the research is innovative (e.g., proposes new paradigms, challenges existing paradigms, or is otherwise highly creative).

  - To what extent the proposed research represents more than an incremental advance upon published data.

- **Research Strategy and Feasibility**

  - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.

  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses, including statistical analyses, are developed.

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

  - Whether the application has provided sufficient evidence to support availability of and access to the populations/samples/resources required for the study.

  - Whether the application includes an appropriate statistical plan with power analysis (if applicable).

  - If applicable, how well the application describes components to increase the impact of the project, including cell line authentication, proper design of animal studies to achieve reproducible and rigorous results in accordance with the ARRIVE guidelines (http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf), and/or experiments to address clinical relevance.

- **Clinical Strategy** (*for applications <u>with</u> a clinical trial*)

  - Whether the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.

- Whether the clinical trial is designed with appropriate study variables, controls, and endpoints.

- How the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.

- Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approvals), if appropriate.

- Whether the application sufficiently demonstrates that the clinical trial can be initiated in the first year of the award.

- Whether potential challenges and alternative strategies are appropriately identified.

- **Transition Plan**

  - How well the application demonstrates feasible methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.

  - Whether the proposed transition plan includes evidence that the PI has or can secure additional funding, or whether the plan clearly describes potential options to secure the additional funding needed to bring the outcomes to the next phase of development.

  - Whether the collaborations and other resources described are sufficient to provide continuity of development.

  - How well the plans are described for distribution of the findings or intervention to the prostate cancer community.

- **Personnel**

  - To what extent the research team's background and prostate cancer- and health disparity-related expertise are appropriate with respect to its ability to perform the proposed work.

  - To what extent the levels of effort are appropriate for successful conduct of the proposed work.

    New Investigators category only:

    – How well the PI's record of accomplishment demonstrates his/her potential for contributing to the prostate cancer health disparity research field and completing the proposed work.

    – How well the proposed contributions of required collaborator(s) included on the research team will appropriately complement the PI's ability to perform the proposed work.

– Whether the collaboration between the PI and the collaborator(s) have the potential to be successful.

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

- **Ethics and/or Regulatory Issues**

  o Whether potential problems regarding ethics, information privacy, and assessment of risk versus benefit of participation have been adequately considered (if applicable).

- **Environment**

  ○ To what extent the scientific environment is appropriate for the proposed research.

  ○ How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

  ○ To what extent the quality and extent of organizational support are appropriate.

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

- **Data Resource Sharing**

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

- **Budget**

  ○ Whether the **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.

  ○ Whether the budget is appropriate for the proposed research.

- **Application Presentation**

  ○ To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers

- Relevance to the mission of the DHP and FY18 PCRP, as evidenced by the following:

- Adherence to the intent of the award mechanism

- Relative impact and innovation

- Program portfolio composition with consideration of New and Established Investigators

- Programmatic relevance to the PCRP Overarching Challenges

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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and PCRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***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 http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement 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 <u>Section I, Overview of the Funding Opportunity</u>.

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 will be made no later than September 30, 2019. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

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 Organizations: Awards 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.

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

II.F.1.a. PI Changes and Award Transfers

New Investigators: Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Established Investigators: Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter 1, 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 USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D 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.

For all awards including prospective accrual of human subjects, quarterly technical progress reports will be required.

Award Chart: An Award Chart will be required within 20 business days after award, and with the submission of each annual written progress report. For the Health Disparity Research Award mechanism, use the generic format example titled, "Award Charts," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template titled, "Award Expiration Transition

Plan," available on the on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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 $10,000,000 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 Terms and Conditions (see General Application Instructions, Section III.A.4).

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 20180329g. The Program Announcement numeric version code will match the General Applications Instructions version code 20180329.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.

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

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

II.H.2.b. Modification

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

- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY18 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 FY18 PCRP Programmatic Panel members can be found at http://cdmrp.army.mil/pcrp/panels/panel18*.

- The application fails to conform to this Program Announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- 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.

- An application for which the PI does not meet the eligibility criteria.

- The application does not address at least one of the FY18 PCRP Overarching Challenges.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	Transition Plan: Upload as Attachment 8 with file name "Transition.pdf."	
	Statement of Independence (required for New Investigators only): Upload as Attachment 9 with file name "Independence.pdf," if applicable.	
	Representations (Extramural submissions only): Upload as Attachment 10 with file name "MandatoryReps.pdf," if applicable.	
	DoD Military Budget Form(s): Upload as Attachment 11 with file name "MFBudget.pdf," if applicable.	
Research & Related Personal Data	Complete form as instructed.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	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	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 DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

APPENDIX 1: ACRONYM LIST

AACR MICR	American Association for Cancer Research, Minorities in Cancer Research
ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
AORTIC	African Organization for Research and Training in Cancer
ARRIVE	Animal Research Reporting In Vivo Experiments
CDPR	Community Based Participatory Research
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CPCRN	Cancer Prevention and Control Research Network
CRCHD	Center to Reduce Cancer Health Disparities
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
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
FAQs	Frequently Asked Questions
FDA	Food and Drug Administration
FSD	Federal Services Desk
FY	Fiscal Year
GSA	General Services Administration
HDRA	Health Disparity Research Award
HRPO	Human Research Protection Office
HSRA	Health Resources and Services Administration
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LGBT	Lesbian, Gay, Bisexual, and Transgendered

LOI	Letter of Intent
M	Million
MADCAP	Men of African Descent and Carcinoma of the Prostate
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NIMHD	National Institute on Minority Health and Health Disparities
NLM	National Library of Medicine
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PCaP	North Carolina – Louisiana Prostate Cancer Project
PCBN	Prostate Cancer Biorepository Network
PCCTC	Prostate Cancer Clinical Trials Consortium
PCRP	Prostate Cancer Research Program
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, Mathematics
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
USUHS	Uniformed Services University of the Health Sciences
VA	Department of Veterans Affairs