Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Dr. Barbara Terry-Koroma*

Health Disparity Research Award

Funding Opportunity Number: W81XWH-16-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), June 9, 2016

- **Invitation to Submit an Application:** late June 2016

- **Application Submission Deadline:** 11:59 p.m. ET, August 25, 2016

- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, August 30, 2016

- **End of Application Verification Period:** 5:00 p.m. ET, August 30, 2016

- **Peer Review:** October 2016

- **Programmatic Review:** December 2016

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*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 DoD 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.

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I.   FUNDING OPPORTUNITY DESCRIPTION

A.   Program Description

Applications to the Fiscal Year 2016 (FY16) Prostate Cancer Research Program (PCRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity 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 FY15 totaled $1.45 billion. The FY16 appropriation is $80 million (M).

The mission of the FY16 PCRP is to find and fund research that will lead to the elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. Specifically, the PCRP seeks to promote highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; multidisciplinary, synergistic research; translational studies to support the fluid transfer of knowledge between bedside and bench; research on patient survivorship and quality of life; the next generation of prostate cancer investigators through mentored research; and research on disparities in the incidence and mortality of prostate cancer.

PCRP Overarching Challenges *(revised for FY16):* Consistent with the program's mission to eliminate death from prostate cancer and enhance the well-being of men experiencing the impact of the disease, investigators are strongly encouraged to address one or more of the following FY16 PCRP overarching challenges:

- Distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer
- Develop strategies to prevent progression to lethal prostate cancer
- Develop effective treatments and address mechanisms of resistance for men with high-risk or metastatic prostate cancer
- Develop strategies to optimize the physical and mental health of men with prostate cancer

PCRP Focus Areas: All applications for the FY16 PCRP funding opportunities are also expected to address at least one of the following FY16 PCRP focus areas:

- **Biomarker Development:** Validation and qualification of biomarkers for early detection of clinically relevant disease or for prognosis or prediction and assessment of response to therapies.
- **Genetics:** Understanding host or tumor genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for clinically relevant prostate cancer.

- **Imaging:** Development of new anatomic, functional, and molecular imaging approaches for the detection and management of clinically relevant prostate cancer.

- **Mechanisms of Resistance and Response:** Understanding primary and acquired resistance as well as exceptional response to therapy.

- **Survivorship and Palliative Care:** Improving the quality of life and well-being of prostate cancer patients and their families.

- **Therapy:** Identification of targets and pathways, and optimization (including sequencing and combination therapies) of therapeutic modalities for prostate cancer, including metastatic prostate cancer.

- **Tumor and Microenvironment Biology:** Understanding the intrinsic and extrinsic mechanisms contributing to tumor development and the progression of prostate cancer.

B.   Award Information

The PCRP Health Disparity Research Award mechanism was first offered in FY01. Since then, 442 Health Disparity Research Award applications have been received, and 80 have been recommended for funding.

The Health Disparity Research Award supports new ideas based on *innovative* concepts or methodologies for health disparity research with the potential to make an important contribution toward eliminating death from prostate cancer and enhancing the well-being of men impacted by the disease. Studies proposed for this award mechanism are expected to improve the understanding of, and ultimately contribute to eliminating disparities in prostate cancer incidence, morbidity, mortality, and survivorship. *Applicants for this award must explicitly state how the proposed research is related to an area of prostate cancer health disparity.* Appropriate health disparity areas include, but are not limited to: race and ethnicity; socioeconomic status; access to health care; differing standards of health care; insurance status; age; geography; sexual orientation; gender identity; and cultural beliefs. Because of the emphasis on innovation, the inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the Principal Investigator (PI) or a member(s) of the research team.

The PCRP seeks applications from investigators from a spectrum of disciplines including, but not limited to, basic science, engineering, bioinformatics, population science, translational research, and clinical research, provided they are appropriately focused on an issue of prostate cancer health disparity. *In addition, all applications are expected to be relevant to one or more of the PCRP focus areas and are encouraged to be responsive to one or more of the PCRP overarching challenges.* If the proposed project does not address one of the overarching challenges, the application must describe how the project will nevertheless address a critical disparity-related need in the field of prostate cancer research and/or patient care.

The Health Disparity Research Award also emphasizes the potential impact, both short-term and long-term, of the research project in reducing or eliminating prostate cancer health disparities. 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) (http://www.ncla-pcap.org) 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 and that apply state-of-the art genomic and/or proteomic analysis, bioinformatics, and/or mathematical models to such data are also encouraged.

New Investigators: This award encourages applications from investigators in the early stages of their careers. The New Investigator category is designed to allow PIs, *early in their faculty appointments or in the process of developing independent research careers*, to compete for funding separately from established investigators. PIs using the New Investigator category are strongly encouraged to strengthen their applications by including investigators experienced in prostate cancer research and/or possessing other relevant expertise as demonstrated by a record of funding and publications. It is the responsibility of the PI to describe how additional investigators will augment his/her expertise and better address the research question. PIs may choose to employ both the New Investigator category and the Qualified Collaborator Option (described below) in a single application. All applicants for the New Investigator category must meet specific eligibility criteria, as described in Section I.C., Eligibility Information.

The Health Disparity Research Award offers two additional options for consideration:

1. *Qualified Collaborator Option:* The Health Disparity Research Award strongly supports collaborative research involving basic, population science, and clinical researchers; researchers with prostate cancer expertise and those with health disparity expertise; and/or researchers and community organizations that may be critical to the study of populations disproportionately affected by prostate cancer. Although these and other types of collaborations are, in general, strongly encouraged, collaborations that meet specific criteria will qualify for a higher level of funding, as described in Section I.D., Funding. For the application to qualify for a higher level of funding, the PI must submit a Qualified Collaboration Statement that clearly describes the proposed collaborator and collaboration and addresses how each of the criteria below are met. In addition, the collaborator must provide a letter of collaboration describing his/her involvement in the proposed work. It should be clear from both documents that the successful completion of the project depends on the unique skills and contributions of both the PI and the qualified collaborator.

   The following criteria must be met to use the Qualified Collaborator Option:

   o The collaborator must significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement. This is expected to include *both* intellectual input and research resources (e.g., supplies, reagents, equipment, personnel, services, tissue samples, or access to patients or populations).

   o The collaborator must contribute at least a 10% level of effort to the project. Contribution of the collaborator should be reflected in the application budget.

o   If the PI does not have experience in prostate cancer research and/or working with disproportionately affected populations, the collaborator must possess such experience.

2. *Nested Young Investigator Option***:** This award also supports the incorporation of young investigators into the research project in order to provide highly motivated predoctoral and postdoctoral scientists experience in prostate cancer health disparity research. The young investigator is not required to have previous health disparity or prostate cancer research experience, but should have a sincere interest in pursuing a career in resolving disparities in prostate cancer incidence, morbidity, mortality, and survivorship. This option primarily provides additional funding to support the salary of the young investigator who will be working on the proposed research project. In addition, an individualized researcher development plan focused in prostate cancer disparities must be described, and should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise that will enable the young investigator to successfully complete the proposed research project and foster the young investigator's development as a prostate cancer health disparity researcher. *Only one predoctoral or postdoctoral young investigator may be included per application.*

Research involving human subjects is permitted under this funding opportunity, but is restricted to studies without clinical trials. Correlative studies associated with an existing clinical trial are particularly encouraged, provided that they are determined to be no greater than minimal risk by the Institutional Review Board (IRB) of record and the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO). A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. PIs seeking funding for a clinical trial are encouraged to consider submitting an application to the FY16 PCRP Impact Award.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC ORP, HRPO prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. 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*. Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional 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 General Application Instructions, Appendix 6, 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 (CDMRP): Search the CDMRP awards database at http://cdmrp.army.mil.

- The North Carolina – Louisiana Prostate Cancer Project (PCaP): 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 http://www.ncla-pcap.org/.

- The Prostate Cancer Biorepository Network (PCBN): 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

- National Institute on Minority Health and Health Disparities (NIMHD) Community Based Participatory Research (CBPR) Initiative: Contact the NIMHD

at http://www.nimhd.nih.gov/programs/extra/cbpr.html for information on current CBPR programs and scientists and communities engaged in health disparity research.

- Uniformed Services University (USU) Center for Health Disparities: Search for programs and communities engaged in health disparity research at http://www.usu-chd.org/Home.

- 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.

- Intercultural Cancer Council (ICC): Search for regional resources and community-based organizations at http://iccnetwork.org/.

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

- National Institutes of Health 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 governmentfunded investigators through DTIC Technical Reports at http://www.dtic.mil/dtic/.

- National Library of Medicine, National Institutes of Health, 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

- International Cancer Research Partnership: Search for investigators and studies, relevant to health disparity, 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 LBGT research, policy, education, and training search http://www.healthhiv.org/sites-causes/national-coalition-for-lgbt-health/.

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

In addition, PIs 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 or other organizations that may provide an avenue for collaborations to facilitate applicable studies.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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 4, Section K.

C. Eligibility Information

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

- **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;

  ○ Either completed at least 3 years of postdoctoral training or fellowship (if never held an independent faculty position), or been in an independent faculty position (or equivalent) for less than 5 years.

  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.

- **Qualified Collaborator Option**

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

- **Nested Young Investigator Option**

  The proposed young investigator must meet the eligibility requirements for one of the following categories:
  ○ Predoctoral Ph.D., M.D. (or equivalent), and M.D./Ph.D. (or equivalent) investigators:

- Be a graduate student enrolled full-time in an accredited doctoral program;

- Will have successfully completed comprehensive examinations or otherwise met candidacy requirements by March 31, 2017.

  ○ Postdoctoral Ph.D., M.D. (or equivalent), and M.D./Ph.D. (or equivalent) investigators:
    - Will have successfully defended a doctoral thesis or possess an M.D. degree by March 31, 2017;

    - Will have 3 years or less of postdoctoral fellowship experience by March 31, 2017.

- Cost sharing/matching is not an eligibility requirement.

- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.

- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. ***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.***

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

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

- **Standard Award Option:**
  ○ The anticipated direct costs budgeted for the entire period of performance will not exceed **$450,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$450,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.

- **Qualified Collaborator Option**:
  ○ The anticipated direct costs budgeted for the entire period of performance will not exceed **$600,000**. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. An application requesting the higher level of funding that does not include a qualified collaborator who meets the specified criteria may be funded at the lower level.

- **Nested Young Investigator Option**:
  - Additional funding can be requested above the maximums specified for the standard award or Qualified Collaborator Option. The anticipated direct costs budgeted for the entire period of performance to specifically support this option will not exceed **$92,500** for a predoctoral investigator or **$115,000** for a postdoctoral investigator plus indirect costs in accordance with each organization's negotiated rate. An application requesting a higher level of funding to support this option, but that does not have the option recommended for funding during programmatic review, may be funded at the lower level.

- All direct and indirect costs of any subaward (subgrant or subcontract) 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 (other than costs for clinical trials, which are not allowed)

- Purchase of data sets and databases

- Support for multidisciplinary collaborations, including travel

- Travel costs for up to 1 investigator to travel to 1 scientific/technical meeting per year. *The Government reserves the right to direct the selection of one of these meetings, should a PCRP-sponsored meeting be convened during the award period of performance*.

For an application including the *Nested Young Investigator Option*, additional costs must be clearly identified as such in the requested budget and budget justification. To support this option, direct costs may be requested for (not all-inclusive):

- Salary/stipends for the young investigator only

- Research workshops for the young investigator

- Travel costs for the young investigator to travel to 1 scientific/technical meeting per year.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.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 Section II.C.4. of the General Application Instructions***.

The CDMRP expects to allot approximately $5.76M of the $80M FY16 PCRP appropriation to fund approximately 6 Health Disparity Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. 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).

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity 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/Funding Opportunity.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit 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 deadline.

Application viewing, modification, and verification in eBRAP is 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. After the end of the application verification period, the full application cannot be modified.

A.   Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-PCRP-HDRA in Grants.gov (http://www.grants.gov/).

B.   Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations 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.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

When starting the pre-application, PIs should ensure that they have selected the appropriate application category and option(s), if applicable:

- Health Disparity Research Award - **Established Investigator**;

- Health Disparity Research Award - **Established Investigator** with Qualified Collaborator Option;

- Health Disparity Research Award - **Established Investigator** with Nested Young Investigator Option;

- Health Disparity Research Award - **Established Investigator** with Qualified Collaborator and Nested Young Investigator Options;

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

- Health Disparity Research Award - **New Investigator** with Qualified Collaborator Option;

- Health Disparity Research Award - **New Investigator** with Nested Young Investigator Option; or

- Health Disparity Research Award - **New Investigator** with Qualified Collaborator and Nested Young Investigator Options

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**

- **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 either be 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 either be 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.

  - ○ [FY16 PCRP Programmatic Panel members](#) should not be involved in any preapplication or application. For questions related to Programmatic Panel members and pre-applications or applications, refer to [Section IV.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 application preparation, research, or other duties for submitted applications. For FY16, 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 conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest (COIs)**
  - ○ 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 Appendix 1, Section C of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

  Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  Preproposal Narrative (two-page limit): The Preproposal Narrative page limit 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 Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - ○ **Rationale:** Clearly articulate the rationale for the project by presenting the ideas and reasoning that support it; include relevant literature citations.
  - ○ **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
  - ○ **Research Approach:** State the project's specific aims and briefly describe the experimental approach to accomplishing the aims. *This award cannot be used to conduct clinical trials.*
  - ○ **Innovation:** Describe how the proposed study is innovative.
  - ○ **Impact:** Describe 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.

  Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to:

  - ○ 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.
  - ○ References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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 used in the Preproposal Narrative.

- Key Personnel Biographical Sketches (five-page limit per individual). All biographical sketches should be uploaded as a single combined file. Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- *For New Investigators only*, append to the PI's biographical sketch a completed Eligibility Statement using the template available for download on the Full Announcement page under this funding opportunity in Grants.gov. The Eligibility Statement must be signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met at the application submission deadline.

List of Individuals Providing Confidential Letters of Recommendation *(for the Nested Young Investigator Option only)***:** Enter contact information for **up to three individuals,** who will provide letters of recommendation. One of the letters of recommendation must be provided by the young investigator's mentor (i.e., the PI of this application). Each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter.

- **Tab 6 – Submit Pre-Application**
  - This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the PCRP, pre-applications will be screened based on the following criteria:

  - **Intent of the Award Mechanism:** Whether the proposed study is sufficiently related to an area of prostate cancer health disparity.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the title page of this Program Announcement/Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the System for Award Management (SAM) well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

Applications will not be accepted unless the PI has received notification of invitation.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

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 Grants.gov application package for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/). For the Health Disparity Research Award, additional application components are also required and should be submitted as directed below.

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form 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*.

Grants.gov application package components: For the FY16 PCRP Health Disparity Research Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition,

Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov 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, etc.) 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; include an explanation of 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.

  - **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, in sufficient detail for scientific review. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable. 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). Clearly identify the source of any proposed cell lines, and whether they were recently authenticated and/or tested for mycoplasma contamination, if applicable. Describe how the clinical relevance of the anticipated findings will be determined, if applicable. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award cannot be used to conduct clinical trials.***

  - **Collaboration (if applicable; encouraged for New Investigators):** Describe the specific contributions of any collaborator(s), other than those included under the Qualified Collaborator Option (which should be described in the Qualified Collaboration Statement), to the research project.

  - **Overarching Challenges and Focus Areas:** Describe how the proposed research is relevant to at least one of the PCRP focus areas and responsive to one of the PCRP overarching challenges. If the proposed project does not address any of the overarching challenges, describe how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.***

  o 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).

  o 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/Funding Opportunity, 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.C., 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: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

- *Qualified Collaborator Option (if applicable):* If applying for the higher level of funding, the Qualified Collaborator *must* provide a letter describing his/her involvement in the proposed work. It should be clear that the success of the project depends on the unique skills and contributions of the collaborator.

- *New Investigators (if applicable):* Investigators applying for the New Investigator category are strongly encouraged to provide a signed letter from each collaborating individual or organization that describes how he/she will support the project, to include unique expertise and/or availability of and access to research resources.

- *Other:* For all other investigators, provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

o Intellectual Property

- Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:

  - Clearly identify all such property;

  - Identify the cost to the Federal government for use or license of such property; or

  - Provide a statement that no property meeting this definition will be used on this project.

- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

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

o 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 4, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **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 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.

- Impact: Describe 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 for Basic Research." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

- **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).

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

  o *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).

  o *PCRP Overarching Challenges and Focus Areas:* Summarize how the proposed project addresses at least one of the PCRP Focus Areas and one or more of the PCRP overarching challenges. If the proposed project does not address at least one of the overarching challenges, describe how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care.

- **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 PI frame the innovative features of his/her 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 (Qualified Collaborator Option only): Qualified Collaboration Statement (one-page limit): Upload as "QualCollab.pdf."**

  If applying for the Qualified Collaborator Option and the higher level of funding, the PI must submit a statement that identifies the qualified collaborator and addresses all criteria, as described in <u>Section I.B., Award Information</u>. It should be clear that the success of the project depends on the unique skills and contributions of both the PI and the qualified collaborator.

- **Attachment 9** *(Only applicable and required for applications submitted under 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). The Statement of Independence must also be signed by the investigator's current mentor/supervisor.

- **Attachment 10** *(Nested Young Investigator Option only)***: Researcher Development Plan: Combine the elements described below and upload as a single file named "YIResearchDev.pdf."**

  Start each document on a new page. If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Although there is no overall page limit for this attachment, some components have page limits that must be followed.*

  The Researcher Development Plan should include the following elements:

  - **Young Investigator Narrative (three-page limit):** *Failure to adhere to the page limitation for the Young Investigator Narrative will result in administrative removal of the young investigator option from the application.*

    The young investigator must describe his/her career goals and his/her role in the PI's proposed research project. The Young Investigator Narrative must be written by the young investigator while also showing evidence of appropriate direction from the PI, who will serve as the mentor for this project.

    – **Young Investigator:** The young investigator should describe his/her career goals and how the mentor's proposed research project and mentoring experience will promote his/her career development in prostate cancer health disparity research. The young investigator should discuss his/her career/research plans after the completion of this award.

    – **Researcher Development Plan:** Clearly articulate a strategy for acquiring the necessary skills, competence, and expertise to successfully contribute to the mentor's research project. Describe how the individualized researcher development plan will provide the young investigator with an opportunity to investigate a problem or question in the field of prostate cancer health disparities, and effectively prepare him/her for a career as an independent prostate cancer health disparity researcher. Explain how the researcher

development plan is supported by the environment; this should include a description of ongoing research on disparities in the incidence, morbidity, mortality, and survivorship of prostate cancer at the organization. Include information on collaborations with other investigators, seminars, workshops, and other opportunities to interact with leaders in the prostate cancer field.

- − **Mentor:** Describe the mentor's background and experience in prostate cancer health disparity research. Explain how the mentor will assist the young investigator throughout the period of performance in developing toward independence in prostate cancer health disparity research. Provide details on the amount and types of interaction between the mentor and the young investigator.

- − **Research Project:** Describe the young investigator's role in the mentor's proposed research project.

- ○ **Transcripts (no page limit):** Include a copy of the proposed young investigator's transcripts from all undergraduate (for predoctoral investigators) or graduate (for postdoctoral investigators) institutions attended. All foreign language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the Full Announcement page in Grants.gov) in place of the transcript.

- ○ **Statement of Work (one-page limit):** Outline the specific portions of the PI's Statement of Work in which the young investigator will be involved. Refer to the General Application Instructions, Section II.C., for detailed information.

- ○ **Eligibility Statement (one-page limit):** Use the Eligibility Statement template for young investigators (available for download on the Full Announcement page under this funding opportunity on Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met.

- • **Attachment 11: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as "MFBudget.pdf."** If a Military Facility (military health system facility, research laboratory, 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 Collaborating DoD Military Facility Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., 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 five-page National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

  Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- 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."

  o Include biographical sketches for the Qualified Collaborator and/or Nested Young Investigator, if applicable.

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

  o Include previous/current/pending support for the Qualified Collaborator and/or Nested Young Investigator, if applicable.

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.

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

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.

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

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 11, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. 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 II.C.7., for detailed information.

> **Additional Application Components:**

In addition to the complete Grants.gov application package, the *Nested Young Investigator Option* also requires submission of confidential letters of recommendation to support the young investigator. The letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files to eBRAP by 5:00 p.m. ET on the last day of the verification period. The PI should monitor whether the letters have been received in eBRAP by viewing the status in the "Pre-Application Files" tab of the pre-application; however, the PI will not be able to view these letters.

The confidential letters should include the following (2-page limit per letter recommended):

- *A letter of recommendation from the PI (mentor)*, describing his/her commitment to the young investigator's career development and mentorship in prostate cancer health disparity research. The mentor's letter(s) should address the following:
  - The young investigator's potential to become a successful and independent prostate cancer researcher focused on disparities in the incidence, morbidity, mortality, and survivorship of prostate cancer;
  - The commitment of the mentor(s) to the career development and mentorship of the young investigator;
  - The mentoring environment, including ongoing prostate cancer research by the mentor and in the organization as a whole, resources available, and how this environment will promote the development of the young investigator as a prostate cancer health disparity researcher; and
  - How the individualized researcher development plan will facilitate the young investigator's development as a successful prostate cancer health disparity researcher.
- *Additional confidential letters of recommendation (one is required; two are allowed)*. Additional letters should describe the young investigator's unique qualifications and accomplishments that highlight his/her potential for success in pursuing a research career focused on disparities in the incidence, morbidity, mortality, and survivorship of prostate cancer. Specifically, each letter should offer the writer's perspective on:
  - The young investigator's qualifications, characteristics, and achievements;
  - The young investigator's potential for productivity and desire for establishing a successful career in prostate cancer health disparity research;
  - The relevance of the proposed research project to providing experience in research focused on prostate cancer disparities; and
  - The suitability of the mentor and environment for providing the young investigator with a solid foundation in prostate cancer health disparity research.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity 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/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission rejection.

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All extramural applications must be submitted through Grants.gov. 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. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. 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 DHA RDA Directorate 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/Funding Opportunity. 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 III.B.2., 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 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 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 Title 18 United States Code 1905.

B. Application Review Process

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria. Of these criteria, Innovation and Impact are equally 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 significant reduction or elimination of disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship.

   - **Innovation**
     - How the research 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 PI acknowledges potential problems and addresses alternative approaches.

- If applicable, how well the PI has included 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.

- **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.

    *Qualified Collaborator Option only***:**

    – Whether the qualified collaborator's experience, expertise, and involvement in the study significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.

    – Whether the collaborator is contributing both intellectual input and research resources to the project.

    – Whether the collaborator's level of effort meets the required minimum of 10% and is appropriate to the proposed collaboration.

    – Whether the collaborator has experience in prostate cancer research or working with disproportionately affected populations to augment the PI's lack of experience in these areas.

    New Investigators only:

    – How 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.

    – If applicable, how well the proposed contributions of collaborators included on the research team will appropriately complement the New Investigator's ability to perform the proposed work.

The following separately scored criteria evaluate only the merits of the proposed *Nested Young Investigator*, if applicable. These criteria are considered independent components of the application evaluation and will only be used at the programmatic review level to determine if this option will be funded:

- **Nested Young Investigator:**
  - To what extent the young investigator's achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate a potential for a successful career as a prostate cancer health disparity researcher.

- To what extent the young investigator's stated career goals demonstrate a strong personal commitment to pursuing an independent career in prostate cancer health disparity research.

- To what extent the letters of recommendation from the mentor and others support the young investigator's potential for a highly productive career.

- Whether the proposed young investigator's level of effort is appropriate for the proposed work.

- Whether the mentor describes plans for sufficient involvement in guiding the young investigator toward a successful career as a prostate cancer health disparity researcher.

- How well the young investigator has outlined a detailed, individualized researcher development plan that will effectively prepare him/her for a career in prostate cancer health disparity research.

- To what extent the scientific environment is appropriate for the proposed career development activities, including professional interaction with established prostate cancer health disparity researchers.

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

- **Responsiveness to Overarching Challenges and Focus Areas**
  - How well the proposed research project(s) address at least one of the PCRP focus areas and one or more of the PCRP overarching challenges.

- **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.

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

2. **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:

   a. **Ratings and evaluations of the peer reviewers**

   b. **Relevance to the mission of the DHP and FY16 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 in relation to the PCRP overarching challenges and focus areas

C.   Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D.   Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E.   Notification of Application Review Results

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.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A.   Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

B.   Modification

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

- Documents not requested will be removed.

C.   Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY16 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 FY16 PCRP Programmatic Panel members can be found at http://cdmrp.army.mil/pcrp/panels/panel16.*

- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

- 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 FY16, 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 Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

- The invited application does not propose the same research project described in the pre-application.

- If a clinical trial is proposed, the application will be withdrawn.

- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4, for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

E. Award Transfers

Changes in PI are not allowed for the award recipients using the New Investigator category of this award, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

To assist *New Investigators* who are transitioning into their first independent faculty position, the submitting organization must agree to relinquish the award when the PI obtains an independent faculty position, or equivalent, at another institution, so that it can be transferred to the new institution.

For the transfer of an award that includes a *Nested Young Investigator*, but where the young investigator will not be transferring along with the PI, funds associated with the young investigator option may be removed. Allowing the funds to be used for an alternate young investigator will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210i]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application 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

C. Grants.gov Contact Center

Questions related to 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/Funding Opportunity 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.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	8	*(Qualified Collaborator Option only, if applicable)* Qualified Collaboration Statement: Upload as Attachment 8 with file name "QualCollab.pdf."	
	9	*(New Investigators Only, if applicable)* Statement of Independence: Upload as Attachment 9 with file name "Independence.pdf."	
	10	*(Nested Young Investigator Option only, if applicable)* Researcher Development Plan: Upload as Attachment 10 with file name "YIResearchDev.pdf."	
	11	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 11 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	

Additional Application Components	Upload Order	Action	Completed
Confidential Letters of Recommendation		Confirm upload to eBRAP.	