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-15-PCRP-HDRA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 16, 2015

- **Invitation to Submit an Application:** July 2015

- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, September 24, 2015

- **Application Submission Deadline:** 11:59 p.m. ET, September 24, 2015

- **End of Application Verification Period:** 5:00 p.m. ET, September 29, 2015

- **Peer Review:** November 2015

- **Programmatic Review:** January 2016

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

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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*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.

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I.   FUNDING OPPORTUNITY DESCRIPTION

A.   Program Description

Applications to the Fiscal Year 2015 (FY15) 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, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing 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 FY14 totaled $1.37 billion. The FY15 appropriation is $80 million (M).

The mission of the FY15 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.

The FY15 funding opportunities offered by the PCRP attempt to address these priorities with a reduced number of award mechanisms. The PCRP has consolidated many of the discipline-specific mechanisms that have been offered in prior fiscal years to provide a more simplified funding approach, focused around the program's priorities of innovation, impact, and training. Specific mechanisms also incorporate options to support both individual awards and team-based awards. All mechanisms continue to maintain the program's focus toward meeting the PCRP mission.

PCRP Overarching Challenges

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, including those from disproportionately affected populations, each PCRP funding opportunity either requires or encourages (see Section I.C., Award Information) applications to address one of the following four PCRP overarching challenges:

- Develop better tools for early detection of clinically relevant disease
- Distinguish aggressive from indolent disease in men newly diagnosed with 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

B.   FY15 PCRP Focus Areas *(revised for FY15)*

All applications for the FY15 PCRP funding opportunities are also expected to address at least one of the following 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, including metastatic prostate cancer.

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

C.   Award Information

The PCRP Health Disparity Research Award mechanism was first offered in FY01. Since then, 385 Health Disparity Research Award applications have been received, and 75 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.

The PCRP seeks applications from investigators from a wide 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 of the PCRP overarching challenges. If the proposed project does not address one of the overarching challenges, the application must provide a description to justify 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.D., 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.E., 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:

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).

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.

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 Health Disparity Traineeship Option:*** This award also offers opportunities for training highly motivated graduate students and postdoctoral fellows interested in pursuing a career in resolving disparities in prostate cancer incidence, morbidity, mortality, and survivorship. The trainee is ***not*** required to have previous health disparity or prostate cancer research experience. This option primarily provides salary support for the trainee. An individualized training program in prostate cancer disparities must be described, and may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, clinical responsibilities, grant writing and/or other activities that will provide the trainee with experience in key areas relevant to the proposed work and foster the trainee's development as a prostate cancer health disparity researcher. An environment appropriate to the proposed training must be clearly described. ***Only one traineeship (predoctoral or postdoctoral) may be requested per application. Plans for training and mentorship must be well developed and clearly described by the PI in the application.***

Research involving human subject use is permitted under this funding opportunity, but is restricted to studies <u>without</u> clinical trials; however, correlative studies, including studies with populations from existing clinical trials, are allowed.

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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 5, 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.

Guidelines for Animal Research: 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.nc3rs.org.uk/page.asp?id=1357.

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. 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 3 to 4 months for regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 5, for additional information.

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 highquality 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 at

- 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 3, Section L.

D. 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;

  ○ 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 for this award.

- **Nested Health Disparity Traineeship Option**

  The proposed trainee must meet the eligibility requirements for one of the following categories:

  ○ Predoctoral Ph.D. and M.D./Ph.D. (or equivalent) trainees:

    – 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, 2016.

  ○ Postdoctoral Ph.D., M.D. (or equivalent), and M.D./Ph.D. (or equivalent) trainees:

    – Will have successfully defended a doctoral thesis or possess an M.D. degree by March 31, 2016;

    – Will have 4 years or less of postdoctoral fellowship experience by March 31, 2016.

- Cost sharing/matching is not an eligibility requirement.

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

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

E. Funding

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

- The anticipated direct costs budgeted for the entire period of performance will not exceed **$600,000**. Associated indirect costs can 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 rate exceeding the organization's negotiated rate.

  ○ If requesting the **Qualified Collaborator Option**, the anticipated direct costs budgeted for the entire period of performance will not exceed **$750,000**. 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.

  ○ If using the **Nested Health Disparity Traineeship Option**, additional funding can be requested above the **$600,000** maximums respective to the standard award or Qualified Collaborator Option. The anticipated direct costs budgeted for the entire period of performance will not exceed **$92,500** for a predoctoral trainee or **$115,000** for a postdoctoral trainee plus indirect costs. 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.

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

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

- Salary

- Research supplies

- Equipment

- Clinical research costs (other than costs for clinical trials, which are not allowed)
- Purchase of data sets and databases
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings. ***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 Health Disparity Traineeship 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 trainee only
- Tuition for coursework, seminars, and workshops (including textbooks and/or related materials)

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. 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. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, 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 Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The CDMRP expects to allot approximately $5.8M of the $80M FY15 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.

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.

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.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

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. Any other application component cannot be changed after the end of the application verification period.

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-15-PCRP-HDRA in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

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.

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

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

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

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

- Health Disparity Research Award - **Established Investigator** with Qualified Collaborator and Nested Traineeship 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 Traineeship Option; or

- Health Disparity Research Award - **New Investigator** with Qualified Collaborator and Nested Traineeship 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):

- **Application Information – Tab 1**

- **Application Contacts – Tab 2**
  - 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 SF-424 form). The Business Official must either be selected from the eBRAP 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.

- **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - FY15 PCRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP 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.

- **Conflicts of Interest (COIs) – Tab 4**
  - ○ 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).

- **Pre-Application Files – Tab 5**

  Notes: Upload document(s) 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, etc.) 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 describe the proposed project using the outline below:

  - ○ **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 the disproportionate effects of prostate cancer on specific populations, and ultimately accelerate the overall elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease.

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

  - ○ 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). Upload as "Biosketches.pdf."

- ○ ***For New Investigators only,*** also include with the biographical sketches (after 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 Health Disparity Traineeship 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 trainee'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.

- • **Submit Pre-Application – Tab 6**

  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.

C.   Full Application Submission Content

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

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 provided in Grants.gov 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 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):

3. **SF-424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.C., for detailed information.**

4. **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.

     The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the PI or member(s) of the collaborating team.

     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.nc3rs.org.uk/page.asp?id=1357). 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, provide a description to justify 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.*

  - ○ 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 Patent Abstracts: Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to

five published manuscript(s) must be included in Attachment 2, Supporting Documentation. 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), 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:

  – *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. 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), letters should also describe how the collaboration(s) will be maintained.

  – *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.

- Intellectual Property

  – Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.

- 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 3, Section L 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."** 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 technical abstract is used by all reviewers. Of particular importance, 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: Summarize the impact of the proposed research, if successful, on understanding and ultimately eliminating the disproportionate effects of prostate cancer on specific populations, and ultimately accelerate the overall elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."** 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 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 mechanism, use the SOW format example titled "**S**OW for Basic Research." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., 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).

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

  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 the disproportionate effects of prostate cancer on specific populations, and ultimately accelerate the overall elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease.

  PCRP Overarching Challenges: Summarize how the proposed project addresses one of the PCRP overarching challenges. If the proposed project does not address at least one of the overarching challenges, provide a description to justify 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 collaborating investigator and addresses all criteria, as described in <u>Section I.C., 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** *(New Investigators, only for investigators not yet in an independent faculty position):* **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 Health Disparity Traineeship Option only)***: Nested Health Disparity Traineeship Plan: Combine the elements described below and upload as a single file named "Traineeship.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 Training Plan should include the following elements:

  - ○ **Training Narrative (three-page limit):** ***Failure to adhere to the page limitation for the Training Narrative will result in administrative removal of the traineeship option from the application.***

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

- **Trainee's Career Goals:** The trainee should describe his/her career goals and how the proposed training and research experience will promote his/her career development in prostate cancer health disparity research. The trainee should discuss his/her career/research plans after the completion of this award.

- **Training Plan:** Describe the individualized training plan, which may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, clinical responsibilities, grant writing, and/or other activities. Provide a timeline for the training plan and describe how it is integrated with and designed to support the proposed research. Explain how the training 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 training or collaborations with other investigators.

- **Mentoring Plan:** Describe the mentor's background and experience in providing training in prostate cancer health disparity research. Explain how the mentoring plan will assist the trainee 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 trainee.

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

○ **Transcripts (no page limit):** Include a copy of the proposed trainee's transcripts from all undergraduate (for predoctoral trainees) or graduate (for postdoctoral trainees) 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 earned, and indication of completion of degree), complete and submit the Academic Statement form in place of the transcript. The Academic Statement form is available for download on the Full Announcement page under this funding opportunity on Grants.gov.

○ **Statement of Work (one-page limit):** Outline the specific portions of the PI's Statement of Work in which the trainee will be involved. Also include specific tasks for both the training plans and mentoring plans. Refer to the General Application Instructions, Section II.C., for detailed information.

○ **Eligibility Statement (one-page limit):** Use the Eligibility Statement template for trainees (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. Refer to the General Application Instructions, Section II.C.8., for detailed information.

5. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*

   - 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.

   - 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."

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

6. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., 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.

7. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

8. **R & R Subaward Budget Attachment(s) Form (if applicable):** 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 of forms and attachments, the *Nested Health Disparity Traineeship Option* also requires submission of confidential letters of recommendation to support the trainee. 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.

Confidential Letters of Recommendation (two-page limit per letter recommended):

The letters should include the following:

- *A letter of recommendation from the mentor*, describing his/her commitment to the trainee's training, career development, and mentorship in prostate cancer health disparity research. The mentor's letter(s) should address the following:

  ○ The trainee'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 training, career development, and mentorship of the trainee;

  ○ The training 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 trainee as a prostate cancer health disparity researcher; and

  ○ How the individualized training program will facilitate the trainee'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 trainee'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 trainee's qualifications, characteristics, and achievements;

  ○ The trainee'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 training in research focused on prostate cancer disparities; and

  ○ The suitability of the mentor and training environment for providing the trainee 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, 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 application rejection.

F. Other Submission Requirements

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

All 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 consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and PCRP, and to the specific intent of the award mechanism. The highestscoring applications from the first tier of review are not automatically recommended for funding. 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 nondisclosure 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, Impact and Innovation 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 the disproportionate effects of prostate cancer on specific populations.

- **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.nc3rs.org.uk/page.asp?id=1357), 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 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, if the PI does not have this experience.

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 Health Disparity Traineeship, 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:

- ○ **Health Disparity Traineeship:**

  - – To what extent the trainee'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 trainee'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 trainee's potential for a highly productive career.

  - – Whether the proposed trainee's level of effort is appropriate for successful training and completion of the proposed work.

  - – Whether the proposed mentoring plan provides evidence of sufficient involvement in guiding the trainee toward a successful career as a prostate cancer health disparity researcher.

  - – How well the trainee has outlined a detailed, individualized training 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 training activities, including professional interaction with established prostate cancer health disparity researchers.

- To what extent the track record of the mentor, regarding his/her previous trainees' career achievements and areas of interest, indicate the potential for successfully preparing the trainee for a successful career as a prostate cancer health disparity researcher.

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 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 equally considered criteria are used by programmatic reviewers:

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

   b. **Relevance to the mission of the DHP and FY15 PCRP, as evidenced by the following:**
      - Adherence to the intent of the award mechanism
      - Programmatic relevance in relation to the PCRP overarching challenges and focus areas
      - Relative impact and innovation
      - Program portfolio composition with consideration of new and established investigators

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:

- A FY15 PCRP IP 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 FY15 PCRP IP members can be found at http://cdmrp.army.mil/pcrp/panels/panel15.

- 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).

- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., 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 institutional investigation. The institution 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, 2016. Refer to the General Application Instructions, Appendix 3, 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 3 for general information regarding administrative requirements.

C.   National Policy Requirements

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

D.   Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

E.   Award Transfers

Changes in PI are strongly discouraged for the award recipients using the New Investigator category of this award. Extenuating circumstances necessitating a change of PI will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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 Health Disparity Traineeship, but where the trainee will not be transferring along with the PI, funds associated with the traineeship may be removed. Allowing the funds to be used for an alternate trainee will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. 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

B. 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
>
> 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
SF-424 (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 Health Disparity Traineeship Option only, if applicable)* Traineeship Plan: Upload as Attachment 10 with file name "Traineeship.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.	