

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Dr. Barbara Terry-Koroma¹

Health Disparity Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-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), July 7, 2017
- **Invitation to Submit an Application:** Early August 2017
- **Application Submission Deadline:** 11:59 p.m. ET, September 28, 2017
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, October 3, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, October 3, 2017
- **Peer Review:** November 2017
- **Programmatic Review:** January 2018

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

This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Prostate Cancer Research Program (PCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The PCRP was initiated in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY16 totaled \$1.53 billion (B). The FY17 appropriation is \$90 million (M).

The mission of the FY17 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 bench and bedside; 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.

II.A.1. FY17 PCRP Overarching Challenges and Focus Areas

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, investigators are strongly encouraged to address one or more of the following FY17 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 (*Revised for FY17!*): All applications for the FY17 PCRP funding opportunities are also expected to address at least one of the following FY17 PCRP Focus Areas:

- Data Science and Analytics
- Imaging and Targeted Radionuclide Therapy
- Population Science
- Precision Medicine, Screening, and Surveillance
- Survivorship, including Psychosocial Impact on the Patient and Family
- Therapy and Mechanisms of Resistance and Response
- Tumor and Microenvironment Biology

II.B. Award Information

The PCRP Health Disparity Research Award mechanism was first offered in FY01. Since then, 499 Health Disparity Award applications have been received, and 87 have been recommended for funding.

The anticipated direct costs budgeted for the entire period of performance for an FY17 PCRP HDRA award will not exceed **\$450,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

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/or address factors that contribute to differences in the disease experience across populations, ultimately contributing 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. The PCRP is interested in research that addresses all different aspects that contribute to health disparity in prostate cancer, including social, cultural, and/or biological contributors.***

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, unpublished 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, psycho-oncology, 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 required to include a collaborator (or collaborators), appropriate to the application, who has experience in prostate cancer health disparity research, as demonstrated by a record of funding and publications. It is the responsibility of the PI to describe the potential of the collaboration(s) to be successful and how the collaboration(s) will augment the PI's expertise to better address the research question. PIs may choose to incorporate the required collaborator through the Qualified Collaborator Option (described below), provided the collaborator meets the requirements of the Qualified Collaborator Option. All applicants for the New Investigator category must meet specific eligibility criteria, as described in [Section II.C, Eligibility Information](#).

The Health Disparity Research Award offers two additional options for consideration for both Established Investigators and New Investigators:

- 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 II.D.5, Funding Restrictions](#). 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 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 the plan 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. While the application may include multiple predoctoral or postdoctoral researchers to support the project, ***only one predoctoral or postdoctoral young investigator may be included per application under the Nested Young Investigator Option.***

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 (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. PIs seeking funding for a clinical trial are encouraged to consider submitting an application to the FY17 PCRP Impact Award (Funding Opportunity Number: W81XWH-17-PCRP-IA).

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.

When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP, Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

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

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

- Congressionally Directed Medical Research Programs: Search the CDMRP awards database at <http://cdmrp.army.mil>.
- The North Carolina – Louisiana Prostate Cancer Project: The PCaP was supported by the PCRP to conduct prostate cancer health disparity studies and developed a large biorepository

of health disparity-related epidemiological data and biospecimens that may be requested for use by the research community. Information on PCaP investigators, data, and specimens is available at <http://www.ncla-pcap.org/>.

- The Prostate Cancer Biorepository Network: The PCBN is supported by the PCRP to develop and maintain a multi-institutional prostate cancer biorepository that facilitates the collection, processing, annotation, storage, and distribution of high-quality human prostate cancer biospecimens to be distributed to the prostate cancer research community. The PCBN offers several types of biospecimens that may be useful for health disparity studies. Information on these biospecimens is available at <http://www.prostatebiorepository.org>.
- National Cancer Institute Center to Reduce Cancer Health Disparities (CRCHD): Search for health disparity research and researchers at <http://crchd.cancer.gov/index.html>.
- National Institute on Minority Health and Health Disparities (NIMHD) Community Based Participatory Research (CBPR) Initiative: Contact the NIMHD at <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 of the Health Sciences (USU) Center for Health Disparities: Search for programs and communities engaged in health disparity research at <https://www.usuhs.edu/chd>.
- American Association for Cancer Research, Minorities in Cancer Research (AACR MICR): Search for health disparity research and researchers at http://www.aacr.org/Membership/Pages/Constituency%20Groups/minorities-in-cancer-research_1C81B8.aspx.
- Cancer Prevention and Control Research Network (CPCRN): Contact the CPCRN at <http://cpcrn.org/> for information on community participatory research to reduce cancer in disproportionately affected populations.
- Intercultural Cancer Council (ICC): Search for regional resources and community-based organizations at <https://www.interculturalcancercouncil.org/>.
- Health Resources and Services Administration (HSRA) Office of Minority Health: Search for health disparity programs and funded investigators at <https://www.hrsa.gov/index.html>.
- National Institutes of Health (NIH) Research Portfolio Online Reporting Tool (NIH Reporter): Search for NIH awards at <http://projectreporter.nih.gov/reporter.cfm>.
- Defense Technical Information Center (DTIC): Search for DoD and other Government-funded investigators through DTIC Technical Reports at <http://www.dtic.mil/dtic/>.
- National Library of Medicine, NIH, PubMed: Search for investigators publishing studies on prostate cancer health disparities at <http://www.ncbi.nlm.nih.gov/pubmed>.

- U.S. Department of Education: Search for institutions that may have increased access to disproportionately affected populations at <http://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst.html>.
- International Cancer Research Partnership: Search for investigators and studies relevant to health disparity that are supported by cancer research funders from several countries including the United States, European Union, United Kingdom, and Canada at <https://www.icrpartnership.org>.
- National Coalition for LGBT Health: For more information on programs focused on lesbian, gay, bisexual, and transgendered (LBGT) research, policy, education, and training, search <http://www.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 be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to [Section II.F.1, Federal Award Notices](#).

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

Government Agencies within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

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

Extramural Organization: An eligible non-(DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission:* Application submitted by a non-DoD organization to Grants.gov.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission:* Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.

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

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

II.C.1.b. Principal Investigator:

Although a PI may be eligible for both the Established Investigator and New Investigator categories, only one category may be chosen; the choice of application category is at the 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;
- The PI must be an independent, early-career investigator within 10 years after completion of his/her terminal degree by the time of the application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.

New Investigators working under another investigator are eligible to apply for this award provided they can demonstrate that they have the freedom to pursue independent research goals without formal mentorship. Graduate students and junior postdoctoral fellows (i.e.,

fellows with less than 3 years of postdoctoral training by the application submission deadline) are not eligible to apply as a New Investigator.

For both Established Investigators and New Investigators:

- **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; and
 - Will have successfully completed comprehensive examinations or otherwise met candidacy requirements by March 31, 2018.
- 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, 2018; and
 - Will have 3 years or less of postdoctoral fellowship experience by March 31, 2018.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <http://orcid.org/>.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Extramural organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

There are no limitations on the number of applications for which an investigator may be named as a PI within the category selected for application (i.e., Established Investigator or New Investigator).

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at eBRAP (<https://eBRAP.org>).

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

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

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

Submission is a two-step process requiring both *pre-application* and *full application* as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

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

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.

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

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

eBRAP allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

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

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type may result in delays in processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “*Add Organizations to this Pre-application.*” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY17 PCR Programmatic Panel](#) members should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

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 the following:
 - 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 PCRFP-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, reference title, and reference source, including 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 or on the Funding Opportunities & Forms page in eBRAP. 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 PCR, 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 time frame for notification of invitation to submit an application is indicated in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

II.D.2.b. Step 2: Full Application Submission Content

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. Refer to the General Application Instructions, Section III, 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 full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural

organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines. For the Health Disparity Research Award, additional application components are also required and should be submitted as directed in the [Additional Application Components](#) section.

II.D.2.b.i. Full Application Guidelines

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-17-PCRP-HDRA from Grants.gov (https://www.grants.gov).	Download application package components for W81XWH-17-PCRP-HDRA from eBRAP (https://ebrap.org).
Full Application Package Components	
<p>SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p>Tab 1 – Summary: Provide a summary of the application information. Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable) • Additional Application Component(s) 	<p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites • Other <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>

Extramural Submissions	Intramural DoD Submissions
Application Package Submission	
<p>Submit package components to Grants.gov (https://www.grants.gov). If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need 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.</p>	<p>Submit package components to eBRAP (https://ebrap.org). Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.</p>
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, <i>with the exception of the Project Narrative and Budget Form</i>, may be modified.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, <i>with the exception of the Project Narrative and Budget Form</i>, may be modified.</p>
Further Information	
<p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

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

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

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components:

- **Extramural Applications Only –**

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

- **Extramural and Intramural Applications –**

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (12-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research; 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.***
- **New Investigators:** Name the required collaborator, other than those included under the Qualified Collaborator Option (which should be described in the Qualified Collaboration Statement), and describe the potential of the collaboration to be successful and how the collaborator will support the PI and the research project.
- **Overarching Challenges and Focus Areas:** Describe how the proposed research is relevant to at least one of the FY17 PCRP Focus Areas and responsive to one of the FY17 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:** Combine and upload as a single file named “Support.pdf.” Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

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 Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Support from Population- or Community-Based Organizations (if applicable): In cases where the PI is affiliated with a designated population- or community-based organization (see [Section I.B, Award Information](#)), inclusion of a letter of support from each organization is encouraged. Such letter(s) of support should explain the nature of the PI's relationship to the organization, the involvement of the PI with the affected population or community, the importance of the project within the affected population or community, any long-term application of the project to the affected population or community, and the PI's commitment to the affected population or community and health disparity.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- ***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 Investigator***: Provide a signed letter from each collaborating individual or organization that describes the potential for the collaboration(s) to be successful, and how the collaborator(s) will support the project, to include unique expertise and/or availability of and access to research resources.

- **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
- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

Describe the proposed research project including the following elements:

- Background: Present the ideas and reasoning behind the proposed project.
- Hypothesis/Objective: State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design.
- 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.

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

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

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

Briefly state the methods to be used.

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

Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.

○ **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 disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship in the targeted population(s).
- **PCRP Overarching Challenges and Focus Areas:** Summarize how the proposed project addresses at least one of the FY17 PCRP Focus Areas and one or more of the FY17 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 (only applicable and required for applications submitted under the Qualified Collaborator Option): 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 [Section I.B, Award Information](#). 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 the New Investigator category): Statement of Independence (one-page limit):** Upload as “Independence.pdf.”

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

- **Attachment 10 (Nested Young Investigator Option only): Researcher Development Plan: Combine the elements described below.** 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 the full 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 limit 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 also describe his/her short- and long-term 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 current transcripts from all undergraduate (for predoctoral investigators) or graduate (for predoctoral and 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 SOW 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 and on the Funding Opportunities & Forms page in eBRAP) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met.
- **Attachment 11: DoD Military 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 DoD Military 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 III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

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

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (PDF) that is not editable.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf.”
- Include biographical sketches for the required collaborator (for the New Investigator category), Qualified Collaborator Option, and/or Nested Young Investigator Option, if applicable.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Include previous/current/pending support for the required collaborator (for the New Investigator category), Qualified Collaborator, and/or Nested Young Investigator, if applicable.

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

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

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

submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

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

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

Additional Application Components
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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 (two-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 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 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.

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

Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as

specified in the Program Announcement. *If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

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**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$450,000** direct costs or using an indirect cost 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 cost 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 lower level.

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

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

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

- Salary
- Research supplies

- Equipment
- Research-related subject costs
- Clinical research costs (other than clinical trials, which are not allowed)
- Support for multidisciplinary collaborations, including travel
 - Travel costs one investigator to travel to one 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/stipend for the young investigator only
- Research workshops for the young investigator
- Travel costs for the young investigator to travel to one scientific/technical meeting per year

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.4, for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.4.***

The CDMRP expects to allot approximately \$6.72M of the \$90M FY17 appropriation(s) to fund approximately seven Health Disparity Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following scored criteria. Of these criteria, Impact 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 disparities in prostate cancer incidence, morbidity, mortality, and/or survivorship.
- **Innovation**
 - How the research is innovative (e.g., proposes new paradigms, challenges existing paradigms, or is otherwise highly creative).
 - To what extent the proposed research represents more than an incremental advance upon published data.
- **Research Strategy and Feasibility**
 - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses, including statistical analyses, are developed.
 - How well the 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 (if applicable).

New Investigators Category 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.
- How well the proposed contributions of required collaborator(s) included on the research team will appropriately complement the PI’s ability to perform the proposed work.
- Whether the collaboration between the PI and the collaborator(s) have the potential to be successful.

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 whether 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 short- and long-term 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 **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.
- Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY17 PCRCP, 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 PCRCP overarching challenges and focus areas

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP, and PCRCP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section.II.E.1.b, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review 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 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently \$150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the

research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

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

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

Intramural Organizations: Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

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

II.F.1.a. 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.

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

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.

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

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

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

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

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

Refer to full text of the [USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#) and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. Annual progress reports as well as a final progress report will be required.

In addition to written progress reports, Annual Award Charts will be required. For the HDRA mechanism, use the format example titled, “Generic Award Charts,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations is available in OAR Article I, Section B, in the [July 2016 R&D General Terms and Conditions](#). The applicable Terms and Conditions for for-profit organizations is available in Section 34 of the [February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations](#).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170516b. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

II.H.2. Administrative Actions

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

II.H.2.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.

II.H.2.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.

II.H.2.c. Withdrawal

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

- An FY17 PCRCP 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 FY17 PCRCP Programmatic Panel members can be found at <http://cdmrp.army.mil/pcrp/panels/panel17>.*
- The application fails to conform to this Program Announcement 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 FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- 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 for which the PI does not meet the eligibility criteria will be withdrawn.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance (Extramural submissions only)	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	Qualified Collaboration Statement (<i>required for Qualified Collaborator Option only</i>): Upload as Attachment 8 with file name "QualCollab.pdf," if applicable.	
	Statement of Independence (<i>required for New Investigators only</i>): Upload as Attachment 9 with file name "Independence.pdf," if applicable.	
	Researcher Development Plan (<i>required for Nested Young Investigator Option only</i>): Upload as Attachment 10 with file name "YIResearchDev.pdf," if applicable.	
	DoD Military 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.	

Application Components	Action	Completed
Research & Related Budget (Extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget (Intramural submissions only)	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	
Additional Application Components	Action	Completed
Confidential Letters of Recommendation	Confirm upload to eBRAP.	

APPENDIX 1: ACRONYM LIST

AACR MICR	American Association for Cancer Research, Minorities in Cancer Research
ACURO	Animal Care and Use Review Office
AORTIC	African-Caribbean Cancer Consortium, African Organization for Research and Training in Cancer
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
B	Billion
CBPR	Community Based Participatory Research Initiative
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CPCRN	Cancer Prevention and Control Research Network
CRCHD	Center to Reduce Cancer Health Disparities
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
EC	Ethics Committee
ET	Eastern Time
FY	Fiscal Year
HRPO	Human Research Protection Office
HSRA	Health Resources and Services Administration
IACUC	Institutional Animal Care and Use Committee
ICC	Intercultural Cancer Council
IRB	Institutional Review Board
LBGT	Lesbian, gay, bisexual, and transgendered
M	Million
MADCAP	Men of African Descent and Carcinoma of the Prostate

NIH	National Institutes of Health
NIH Reporter	National Institutes of Health Research Portfolio Online Reporting Tool
NIMHD	National Institute on Minority Health and Health Disparities
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PCaP	North Carolina – Louisiana Prostate Cancer Project
PCBN	Prostate Cancer Biorepository Network
PCRCP	Prostate Cancer Research Program
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
USU	Uniformed Services University of the Health Sciences