

# **Program Announcement**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Prostate Cancer Research Program**

### **Health Disparity Research Award**

**Funding Opportunity Number: W81XWH-12-PCRP-HDRA**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 26, 2012
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, August 9, 2012
- **Application Submission Deadline:** 11:59 p.m. ET, August 9, 2012
- **Peer Review:** October 2012
- **Programmatic Review:** December 2012

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications for the Prostate Cancer Research Program (PCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The PCRP was established in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY11 totaled \$1.13 billion. The FY12 appropriation is \$80 million (M).

The overall goal of the FY12 PCRP is to find and fund research that will lead to the elimination of death and suffering from prostate cancer. Specifically, the PCRP seeks to promote highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; multidisciplinary synergistic research; translational studies to support the fluid transfer of knowledge between bedside and bench; research on patient survivorship and quality of life; the next generation of prostate cancer investigators through mentored research; and research on disparities in the incidence and mortality of prostate cancer.

#### PCRP Overarching Challenges

Consistent with the program's overall goal, each PCRP funding opportunity either requires or encourages (see Award Information below) applications to address one of the following PCRP overarching challenges:

- Develop effective treatments for advanced prostate cancer (i.e., disease progression with no available curative therapy)
- Distinguish aggressive from indolent disease

#### PCRP Focus Areas (*revised for FY12*)

All applications for FY11 PCRP funding opportunities must also address at least one of the following PCRP focus areas:

**Biomarker Development:** Qualification or validation of biomarkers for detection of aggressive disease, prediction and assessment of response to therapies, and prognosis and progression. These include validation studies of circulating tumor cells. Biomarker studies may include discovery if accompanied by qualification or validation.

**Genetics:** Understanding host or tumor genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for aggressive prostate cancer.

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

**Mechanisms of Resistance:** Understanding primary and acquired resistance to therapy.

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

**Therapy:** Identification of new targets, pathways, and therapeutic modalities.

**Tumor and Microenvironment Biology:** Understanding prognosis and progression of prostate cancer.

## B. Award Information

The PCRP Health Disparity Research Award mechanism was introduced in FY01. Since then, 185 applications have been received, and 50 have been recommended for funding.

The Health Disparity Research Award (HDRA) supports new ideas based on innovative concepts or methodologies for prostate cancer health disparity research with the potential to make an important contribution towards eliminating death and suffering from prostate cancer. Studies proposed for this award mechanism are expected to improve the understanding of, and ultimately eliminate, disparities in prostate cancer incidence, morbidity, and mortality. ***Applicants for this award must explicitly state how the proposed research is related to an area of prostate cancer health disparity.*** Appropriate health disparity areas include, but are not limited to, race and ethnicity, socioeconomic status, access to or differing standards of health care, insurance status, age, geography, and cultural beliefs.

The PCRP seeks HDRA applications from the wide spectrum of basic, population-based, translational, and clinical research, provided they are appropriately focused on an issue of prostate cancer health disparity. In addition, all applications must be relevant to at least one of the PCRP focus areas and are encouraged to be responsive to one of the PCRP overarching challenges; however, if the proposed project does not address one of the overarching challenges, the application must provide a description to justify how the project will nevertheless address a critical disparity-related need in the field of prostate cancer research and/or patient care.

***Research involving human subjects is permitted under this funding opportunity but is restricted to studies without clinical trials.*** For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the CDMRP eReceipt System at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/). PIs seeking funding for a clinical trial should consider submitting an application to an alternative FY12 PCRP Program Announcement/Funding Opportunity.

The Health Disparity Research Award offers three additional options for PI consideration:

1. ***Qualified Collaborator Option:*** The HDRA strongly supports collaborative research involving basic, population-based, and clinical researchers, researchers with prostate cancer expertise and those with health disparity expertise, or researchers and community organizations that may be critical to the study of populations disproportionately affected by prostate cancer. Although these and other types of collaborations are, in general, strongly encouraged, collaborations that meet specific criteria will qualify for a higher level of funding as described in [Section I.D., Funding](#). For the application to qualify for a higher level of funding, the PI must submit a Qualified Collaboration Statement that clearly describes the proposed collaborator and collaboration and addresses how each of the criteria below are met. In addition, the collaborator(s) 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 or working with disproportionately affected populations, the collaborator must possess such experience.
2. ***New Investigator Option:*** The HDRA mechanism encourages applications from investigators in the early stages of their careers. The New Investigator Option 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. Applications from New Investigators and Established Investigators will be peer- and programmatically reviewed separately. PIs using the New Investigator Option are strongly encouraged to strengthen their applications by including investigators experienced in prostate cancer research and/or possessing other relevant expertise as demonstrated by a record of funding and publications. It is the responsibility of the PI to describe how additional investigators will augment his/her expertise and better address the research question. PIs may choose to employ both the New Investigator Option and the Qualified Collaborator Option in a single application. All applicants for the New Investigator Option must meet specific eligibility criteria as described in [Section I.C., Eligibility Information](#).
3. ***New for FY12 – Nested Health Disparity Traineeship Option:*** The HDRA offers opportunities for training highly motivated graduate students and postdoctoral fellows interested in pursuing a career in resolving disparities in prostate cancer incidence, morbidity, and mortality. The trainee is ***not*** required to have previous health disparity or prostate cancer research experience. This option primarily provides salary support for the trainee. An individualized training program in prostate cancer disparities must be described, and may include coursework, laboratory techniques, conference, seminars, journal clubs, teaching responsibilities, clinical responsibilities, and/or other activities that will provide the trainee with experience in key areas relevant to the proposed work and foster the trainee’s development as a prostate cancer health disparity researcher. An environment appropriate to the proposed training must be clearly described. ***Only one traineeship (predoctoral or postdoctoral) may be requested per application. Plans for training and mentorship must be well developed and clearly described by the PI for the HDRA Award application.***

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

- Congressionally Directed Medical Research Programs (CDMRP): Search the CDMRP awards database at <http://cdmrp.army.mil>.
- The North Carolina – Louisiana Prostate Cancer Project (PCaP): PCaP was supported by the PCRCP 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/>.

- National Cancer Institute Center to Reduce Cancer Health Disparities (CRCHD): Search for health disparity research and researchers at <http://crchd.cancer.gov/disparities/disparities-index>
- National Center on Minority Health and Health Disparities (NCMHD) Community Based Participatory Research (CBPR) Initiative: Contact the NCMHD at [http://ncmhd.nih.gov/our\\_programs/CommunityParticipationResearch.asp](http://ncmhd.nih.gov/our_programs/CommunityParticipationResearch.asp) for information on current CBPR programs and scientists and communities engaged in health disparity research.
- Uniformed Services University of the Health Sciences (USUHS) Center for Health Disparities: Search for programs and communities engaged in health disparity research at <http://www.usuhs.mil/chd/index>
- American Association of Cancer Research, Minorities in Cancer Research (AACR MICR): Search for health disparity research and researchers at <http://www.aacr.org/home/membership-/association-groups/minorities-in-cancerresearch.aspx>.
- Intercultural Cancer Council (ICC): Search for regional resources and community-based organizations at <http://iccnetwork.org/>.
- National Institutes of Health Research Portfolio Online Reporting Tool (NIH Reporter): Search for NIH awards at <http://projectreporter.nih.gov/reporter.cfm>.
- Defense Technical Information Center (DTIC): Search for Department of Defense (DOD) and other government-funded investigators through DTIC Technical Reports at <http://www.dtic.mil/dtic/>.
- National Library of Medicine, National Institutes of Health, PubMed: Search for investigators publishing studies on prostate cancer health disparities at <http://www.ncbi.nlm.nih.gov/sites/entrez?db=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>
- International Cancer Research Portfolio: Search for investigators and studies, relevant to health disparity, supported by cancer research funders from several countries including the United States, European Union, United Kingdom, and Canada at <http://www.cancerportfolio.org/index.jsp>.

In addition, PIs are encouraged to interact with organizations, as applicable to their proposed studies, such as the Urban League, National Medical Association, National Alliance for Hispanic Health, American Indian Health Care Association, National Rural Health Association, National African American Outreach Program of the Patient Advocate Foundation, Prostate Health Education Network, and international organizations such as The Prostate Net, Prostate Cancer Transatlantic Consortium, African Organization for Research and Training in Cancer, African-Caribbean Cancer Consortium, Men of African Descent and Carcinoma of the Prostate (MADCAP) Consortium, or other organizations that may provide an avenue for collaborations to facilitate applicable studies, e.g., those on aggressive disease.

All investigators applying to FY12 PCRP funding opportunities are encouraged to consider leveraging resources available through the PCRP-funded Prostate Cancer Biorepository Network (PCBN) (<http://www.prostatebiorepository.org>) and/or the North Carolina-Louisiana Prostate Cancer Project (PCaP) (noted above), if retrospectively collected human anatomical substances or correlated data are relevant to the proposed studies.

*The CDMRP intends that data and research resources generated by CDMRP-funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.*

### C. Eligibility Information

*Although a PI may be eligible for both the Established Investigator and New Investigator Option categories, the PI can choose only one category under which to apply. If this is the case, 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 Option:** By the application submission deadline, the PI must have:
  - The freedom to pursue independent research goals without formal mentorship;
  - Not previously received a PCRP Health Disparity Research Award;
  - Either completed at least 3 years of postdoctoral training or fellowship or been in an independent faculty position for less than 5 years.

New Investigators working within a laboratory team are eligible to apply for this award provided that 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 postdoctoral training) are not eligible for this award.

- **Nested Health Disparity Traineeship Option:** The proposed trainee must meet the eligibility requirements for one of the following categories:
  - Predoctoral Ph.D. and M.D./Ph.D. (or equivalent) trainees:
    - Be a graduate student enrolled full-time in an accredited doctoral program;
    - Will have successfully completed comprehensive examinations or otherwise met candidacy requirements by December 31, 2012.
  - Postdoctoral Ph.D., M.D. (or equivalent), and M.D./Ph.D. (or equivalent) trainees:
    - Will have successfully defended a doctoral thesis or possess an M.D. degree by December 31, 2012;
    - Will have 4 years or less of postdoctoral fellowship experience by December 31, 2012.

- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

#### **D. Funding**

- The maximum period of performance is **3** years.
- The maximum allowable direct -or- total costs for the entire period of performance are **\$450,000** plus indirect costs for both Established and New Investigators.
  - If requesting an Optional Qualified Collaborator, the maximum allowable direct costs for the entire period of performance are **\$600,000** plus indirect costs. An application requesting the higher level of funding that does not include a qualified collaborator who meets the specified criteria will have its budget reduced as appropriate.
  - If using the Nested Health Disparity Traineeship Option, additional funding can be requested above the \$450,000 or \$600,000 maximums respective to the standard and Qualified Collaborator Options. The traineeship option provides additional allowable direct costs at a maximum of **\$92,500** for a predoctoral trainee or **\$115,000** for a postdoctoral trainee plus indirect costs. An application requesting a higher level of funding to support this option, but that does not have the option recommended for funding during programmatic review, will have its budget reduced as appropriate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for the PI to attend one DoD PCRP Innovative Minds in Prostate Cancer Today (IMPACT) meeting or other similar event as directed by the CDMRP, if the meeting occurs within the period of performance of the award. The IMPACT meeting is held to disseminate the results of PCRP-sponsored research. Costs associated with travel to this meeting, up to \$1,800, should be included in Year 2 of the budget. These travel costs are in addition to those allowed for annual scientific/ technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies



- Equipment
- Clinical research costs (other than costs for clinical trials, which are not allowed)
- Purchase of data sets and databases
- Travel between collaborating organizations
- Travel costs of up to \$1,800 (or \$3,600 for an application that includes the Qualified Collaborator Option) per year to attend scientific/technical meetings

For an application including the Nested Health Disparity Traineeship Option, additional costs must be clearly identified as such in the requested budget and budget justification. To support this option, direct costs:

Must be requested for:

- Travel for the trainee to attend one DoD PCRP Innovative Minds in Prostate Cancer Today (IMPaCT) meeting or other similar event as directed by the CDMRP, if the meeting occurs within the period of performance of the award. Costs associated with travel to this meeting, up to \$1,800, should be included in Year 2 of the budget. These travel costs are in addition to those allowed for annual scientific/ technical meetings.

May be requested for (not all-inclusive):

- Salary/stipends for the trainee only
- Tuition for coursework, seminars, and workshops (including textbooks and/or related materials)
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

*The CDMRP expects to allot approximately \$4.8M of the \$80M FY12 PCRP appropriation to fund approximately 5 Health Disparity Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.*

## **II. SUBMISSION INFORMATION**

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

### **A. Where to Obtain the Application Package**

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-12-PCRP-HDRA.

## B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<https://cdmrp.org/>).

PIs and organizations identified in the application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

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

- Health Disparity Research Award (i.e., Experienced Investigator);
- Health Disparity Research Award-New Investigator Option;
- Health Disparity Research Award-Qualified Collaborator Option; *or*
- Health Disparity Research Award-New Investigator and Qualified Collaborator Options.

***NOTE: Inclusion of the Nested Health Disparity Traineeship Option does not affect the pre-application category.***

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest – Tab 3**

FY12 PCRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk ([help@cdmrp.org](mailto:help@cdmrp.org) or 1-301-682-5507).

- **Required Files – Tab 4**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

**List of Individuals Providing Confidential Letters of Recommendation (for the Nested Health Disparity Traineeship Option):** The proposed trainee *must* request confidential letters of recommendation through the PI's pre-application. The letters must be provided by the trainee's mentor (i.e., the PI of this application) and up to two other individuals. Requests for confidential letters of recommendation are made by entering into the appropriate CDMRP eReceipt System data fields the name, position title, email address, and phone number for each individual from whom a letter is being requested. The total number of requested letters must not exceed three.

Each individual providing a letter of recommendation will receive an email generated from the CDMRP eReceipt System containing specific instructions on how to upload his/her letter. The PI should monitor via eReceipt whether the letter(s) have been received; however, neither the PI nor the proposed trainee will be able to view the content of the letter(s). The confidential letter(s) of recommendation must be submitted through the CDMRP eReceipt System by 5:00 p.m. ET on the application deadline date.

The confidential letters of recommendation must be submitted by the individuals named in the pre-application. If this is not possible, the PI must contact the CDMRP eReceipt Help Desk for assistance at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507. Specific points to address in the letters of recommendation that are unique to the award mechanism are described under “Application Submission Content and Form” below.

- **Submit Pre-Application – Tab 5**

*This tab must be completed for the pre-application to be accepted and processed by CDMRP.*

- **Other Documents Tab**

No additional documents are required.

### **C. Application Submission Content and Form**

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

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

*New for FY12: Explanation of new requirements.*

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

2. **Attachments Form**

- **Attachment 1: Project Narrative (12-page limit):** Upload as “ProjectNarrative.pdf.”

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

- **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 or Objective:** State the hypothesis to be tested or the objective to be reached.
- **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. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award cannot be used to conduct clinical trials.***
- **Collaboration (if applicable; encouraged for the New Investigator Option):** Describe the specific contributions of any collaborator(s), other than those included under the Qualified Collaborator Option (which should be described in the Qualified Collaboration Statement), to the research project.
- **Overarching Challenges and Focus Areas:** Describe how the proposed research is relevant to at least one of the PCRP focus areas and responsive to one of the PCRP overarching challenges. If the proposed project does not address either of the overarching challenges, provide a description to justify how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must 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, reflecting the laboratory space, equipment, and other resources available for the project.
- 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](#), above), a letter of support from each organization is encouraged. Such letter(s) of support should explain the nature of the PI's relationship to the organization, the involvement of the PI with the affected population or community, the importance of the project within the affected population or community, any long-term application of the project to the affected population or community, and the PI's commitment to the affected population or community and health disparity.
- Letters of Collaboration:
  - ***Qualified Collaborator Option (if applicable):*** If applying for the higher level of funding, the Qualified Collaborator **must** provide a letter describing his/her involvement in the proposed work. It should be clear that the success of the project depends on the unique skills and contributions the collaborator.
  - ***New Investigator Option (if applicable):*** Investigators applying for the New Investigator option are strongly encouraged to provide a signed letter from each collaborating individual or organization that describes how he/she will support the project, to include unique expertise and/or availability of and access to research resources. If the PI is likely to change organizations during the award period of performance (e.g., New Investigators transitioning into their first independent faculty position), describe how the collaboration will be maintained.
  - ***Other:*** For all other investigators, provide a signed letter from each collaborating individual or organization (if applicable) that specifically describes the support to be provided.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”  
The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

- Background: Present the ideas and reasoning behind the proposed project.
- Objective: State the objective to be reached. Provide evidence or rationale that supports the objective.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design.
- Impact: Summarize the potential impact of the proposed project on the elimination of death and suffering from prostate cancer.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”  
Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** The public abstract is used by consumer peer reviewers along with other components of the application package.
  - Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine.***
  - Describe the ultimate applicability of the research.
    - What types of patients will it help, and how will it help them?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
    - If the research is too basic for clinical applicability, describe the interim outcomes.
  - What are the likely contributions of this study to advancing the field of prostate cancer health disparity research?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.

**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 the long-term anticipated advantages that the new understanding may ultimately contribute to the goal of eliminating death and suffering from prostate cancer.

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

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

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

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

- Study concept – Investigation of a novel idea and/or research question.
- Research method or technology – Use of novel research methods or new technologies, including technology development, to address a research question.
- Novel method or technology – Development of a novel method or technology for prevention, detection, diagnosis, or treatment.
- Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- **Attachment 8 (Qualified Collaborator Option only): Qualified Collaboration Statement (one-page limit).** Upload as “QualCollab.pdf.”

If applying for the Qualified Collaborator Option and the higher level of funding, the PI must submit a statement that identifies the collaborating investigator and addresses all criteria as described in [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 (New Investigator Option only): Eligibility Statement (one-page limit).** Upload as “Eligibility.pdf.”

Use the Eligibility Statement template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met at the application submission deadline.

- **Attachment 10 (New Investigator Option, only for investigators not yet in an independent faculty position): Statement of Independence (one-page limit).** Upload as “Independence.pdf.”

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

- **Attachment 11 (Nested Health Disparity Traineeship Option only): Nested Health Disparity Traineeship Plan.**

Combine the elements described below and upload as a single file named “Traineeship.pdf.” Start each document on a new page. If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Although there is no overall page limit for this attachment, some components have page limits that must be followed.*

The Training Plan should include the following elements:

- **Training Narrative (3-page limit):** *Failure to adhere to the page limitation for the Training Narrative will result in administrative removal of the traineeship option from the application.*

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

- **Trainee's Career Goals:** The trainee should describe his/her career goals and how the proposes training and research experience will promote his/her career development in prostate cancer health disparity research. The trainee should discuss his/her career/research plans after the completion of this award.
- **Training Plan:** Describe the individualized training plan, which may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, clinical responsibilities, and/or other activities. Provide a timeline for the training plan and describe how it is integrated with and designed to support the proposed research. Explain how the training plan is supported by the environment; this should include a description of ongoing research on disparities in the incidence and mortality of prostate cancer at the organization. Include information on training or collaborations with other investigators.
- **Mentoring Plan:** Describe the mentor's background and experience in prostate cancer health disparity research. Explain how the mentoring plan will assist the trainee throughout the period of performance in developing toward independence in prostate cancer health disparity research. Provide details on the amount and types of interaction between the mentor and the trainee.
- **Research Project:** Describe the trainee's role in the mentor's proposed research project.
- **Transcripts (no page limit):** Include a copy of the proposed trainee's transcripts from all undergraduate (for predoctoral trainees) or graduate (for postdoctoral trainees) institutions attended. All foreign language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts.  
If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit earned, and indication of completion of degree), complete and submit the Academic Statement form in place of the transcript. The Academic Statement form is available for download on the Full Announcement page in Grants.gov.
- **Statement of Work (one-page limit):** Outline the specific portions of the PI's statement of work for which the trainee will be involved. Also include specific tasks for both the training plans and mentoring plans. Refer to the General Application Instructions, Section II.C., for detailed information.



- **Eligibility Statement (one-page limit):** Use the Eligibility Statement template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
    - PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
    - PI Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
    - Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
    - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
  - 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
  - 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

**Additional Application Components:** In addition to the completed Grants.gov application package of forms and attachments, inclusion of the Nested Health Disparity Traineeship Option also requires the submission of confidential letters of recommendation to support the trainee. One letter must be submitted by the mentor (i.e., the PI of the application) and up to two additional letters of recommendations may be submitted by other individuals; the maximum number of letters is three. All letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files.

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

The letters should include the following:

- ***A letter of recommendation from the mentor***, describing his/her commitment to the trainee’s training, career development, and mentorship in prostate cancer health disparity research. The mentor’s letter(s) should address the following:
  - The trainee’s potential to become a successful and independent prostate cancer researcher focused on disparities in the incidence, morbidity, and mortality of prostate cancer.
  - The commitment of the mentor(s) to the training, career development, and mentorship of the trainee, including details of the proposed interactions of the mentor with the trainee during the training;

- The training environment, including ongoing prostate cancer research in the mentor's laboratory and in the organization as a whole, resources available, and how this environment will promote the development of the trainee as a prostate cancer health disparity researcher;
  - The individualized training program and how it will facilitate the trainee's development as a successful prostate cancer researcher;
  - The mentor's record in training predoctoral and/or postdoctoral fellows;
  - The degree to which the trainee participated in the project development and the degree to which the trainee will participate in the execution of the project if funded.
- ***Additional confidential letters of recommendation (one is required).*** Additional letters should describe the trainee's unique qualifications and accomplishments that highlight his/her potential for success in pursuing a research career focused on disparities in the incidence, morbidity, and mortality of prostate cancer. Specifically, each letter should offer the writer's perspective on:
    - The trainee's qualifications, characteristics, and achievements;
    - The trainee's potential for productivity and desire for establishing a successful career in prostate cancer health disparity research;
    - The relevance of the proposed research project to providing training in research focused on prostate cancer disparities; and
    - The suitability of the mentor and training environment for providing the trainee with a solid foundation in prostate cancer health disparity research.

#### **D. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

#### **E. Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Numbering System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General,

U.S. Army Medical Research and Materiel Command, based on technical merit, the relevance to the mission of the DoD and PCRP and the specific intent of the award mechanism. The highestscoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review 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. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

## **B. Application Review Criteria**

**1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria. Of these Impact and Innovation are equally the most important, with the remaining criteria listed in decreasing order of importance:

- **Impact**
  - How well the proposed research addresses an issue of health disparity in prostate cancer in the affected population or community.
  - To what extent the project could, whether in the short-term or long-term, lead to significant reduction or elimination of the disproportionate effects of prostate cancer on specific populations, and ultimately accelerate the overall elimination of death and suffering from prostate cancer.
- **Innovation**
  - How well the research proposes new paradigms, challenges existing paradigms, or is otherwise highly creative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
  - To what extent the proposed research represents more than an incremental advance upon published data.
- **Research Strategy and Feasibility**
  - How well 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 are developed.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- **Personnel**
  - To what extent the research team's background and prostate cancer- and health disparity-related expertise are appropriate with respect to its ability to perform the proposed work.
  - To what extent the levels of effort are appropriate for successful conduct of the proposed work.
  - ***Qualified Collaborator Option only:***
    - Whether the collaborator's experience, expertise, and involvement in the study significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.
    - Whether the collaborator is contributing both intellectual input and research resources to the project.
    - Whether the collaborator's level of effort meets the minimum 10% and is appropriate to the proposed collaboration.
    - Whether the collaborator has experience in prostate cancer research or working with disproportionately affected populations, if the PI does not have this experience.
  - ***New Investigator Option only:***
    - How the PI's record of accomplishment demonstrates his/her potential for contributing to the prostate cancer research field and completing the proposed work.
    - If applicable, how well the proposed contributions of collaborators included on the research team will appropriately complement the New Investigator's ability to perform the proposed work.

The following scored criterion evaluates only the merits of the proposed Nested Health Disparity Traineeship, if applicable. This criterion is considered an independent component of the application evaluation and will ***NOT*** be incorporated into the overall score:

- **Health Disparity Traineeship:**
  - To what extent the trainee's achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate a potential for a successful career as a prostate cancer health disparity researcher.
  - To what extent the trainee's stated career goals demonstrate a strong personal commitment to pursuing an independent career in prostate cancer health disparity research.

- To what extent the letters of recommendation from the mentor and others support the trainee’s potential for a highly productive career.
- Whether the proposed trainee’s level of effort is appropriate for successful training and completion of the proposed work.
- Whether the proposed mentoring plan provides evidence of sufficient involvement in guiding the trainee toward a successful career as a prostate cancer health disparity researcher.
- How well the trainee has outlined a detailed, individualized training plan that will effectively prepare him/her for a career in prostate cancer health disparity research.
- To what extent the scientific environment is appropriate for the proposed training activities, including professional interaction with established prostate cancer health disparity researchers.
- To what extent the track record of the mentor, regarding his/her previous trainees’ career achievements and areas of interest, indicate the potential for successfully preparing the trainee for a successful career as a prostate cancer health disparity researcher.

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

- **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.

- **Budget**

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

- **Application Presentation**

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

**2. Programmatic Review:** To determine the application’s relevance to the mission of the DoD and PCRCP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- Adherence to the intent of the award mechanism
- Programmatic relevance in relation to the PCRCP overarching challenges and focus areas
- Ratings and evaluations of the peer reviewers
- Relative impact and innovation
- Program portfolio composition

### **C. Recipient Qualification**

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

### **D. Application Review Dates**

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

### **E. Notification of Application Review Results**

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

## **IV. ADMINISTRATIVE ACTIONS**

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

### **A. Rejection**

The following will result in administrative rejection of the application:

- Pre-application is not submitted
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

### **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in [Section IV.A., Rejection](#)). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.
- Attachment 11, the Nested Health Disparity Traineeship Plan, will be removed if the page limitation for the Training Narrative is exceeded or if the proposed trainee does not meet the respective eligibility requirements.

## **C. Withdrawal**

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

- A FY12 PCRP Integration Panel (IP) member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY12 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel12>
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- The proposed research is, or includes, a clinical trial.
- The application does not address an area of prostate cancer health disparity.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

## **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

## **V. AWARD ADMINISTRATION INFORMATION**

### **A. Award Notice**

Awards will be made no later than September 30, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

### **B. Administrative and National Policy Requirements**

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

### **C. Reporting**

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

### **D. Award Transfers**

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

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

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

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



## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System 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: 1-301-682-5507

Email: [help@cdmrp.org](mailto:help@cdmrp.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through the 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: 1-800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
	<i>Qualified Collaborator Option only, if applicable:</i> Upload Qualified Collaboration Statement (QualCollab.pdf) as Attachment 8.	
	<i>New Investigator Option only, if applicable:</i> Upload Eligibility Statement (Eligibility.pdf) as Attachment 9.	
	<i>New Investigator Option only, if applicable:</i> Upload Statement of Independence (Independence.pdf) as Attachment 10, if applicable.	
<i>Nested Health Disparity Traineeship Option only, if applicable:</i> Upload Traineeship Plan (Traineeship.pdf) as Attachment 11.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI 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 Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	
<b>Additional Application Components</b>	<b>Action</b>	<b>Completed</b>
Confidential Letters of Recommendation	Confirm upload to CDMRP eReceipt System.	