# Program Announcement

**Department of Defense Congressionally Directed Medical Research Programs**

**Prostate Cancer Research Program**

**Health Disparity Research Award**

**Funding Opportunity Number: W81XWH-11PCRP-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)**,** May 18, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, June 8, 2011
- **Scientific Peer Review:** July 2011
- **Programmatic Review:** October 2011

***New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.***

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

The Prostate Cancer Research Program (PCRP) was established in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY10 totaled $1.05 billion. The FY11 appropriation is $80 million (M).

The overall goal of the FY11 PCRP is to find and fund innovative, high-impact research that will eliminate death and suffering from prostate cancer. Specifically, the PCRP seeks to support innovative, high-risk, high-gain research with potential near-term impact; sponsor multidisciplinary synergistic research; fund translational studies to promote the fluid transfer of knowledge between bedside and bench; invest in research on patient survivorship (quality of life); foster the next generation of prostate cancer investigators through mentored research; and promote research into prostate cancer health disparities.

**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 relapse with no available curative therapy)
- Distinguish aggressive from indolent disease

**PCRP Focus Areas *(revised for FY11)***

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

**Biomarkers:** Discovery and validation of biomarkers for the detection, prediction of response to therapy, prognosis, and progression of prostate cancer.

**Genetics:** Understanding the genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for clinically significant prostate cancer.

**Imaging:** Development of new anatomic and molecular imaging technology for the detection and management of prostate cancer.

**Survivorship:** Studies on the impact of treatment, nutrition, metabolism, and exercise on the well-being of prostate cancer patients and their families.

**Therapy:** Identification of new targets, pathways, and therapeutic modalities, including immunotherapy and mechanisms of resistance.

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

## B. Award Information

The PCRP Health Disparity Research Award mechanism was introduced in FY01. Since then, 177 applications have been received, and 45 have been recommended for funding.

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

The PCRP seeks Health Disparity Research Award applications from the wide spectrum of basic to clinical research, provided they are appropriately focused on an issue of prostate cancer health disparity. In addition, all applications (1) should be relevant to at least one of the PCRP focus areas, and (2) are encouraged, although not required, to be responsive to one of the PCRP overarching challenges.

***Research involving human subject use is permitted under this funding opportunity, but is restricted to studies <u>without</u> clinical trials.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical research, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/. Principal Investigators (PIs) seeking funding for a clinical trial should consider submitting an application for the FY11 PCRP Clinical Trial Award.

PIs wishing to apply for funding for population-based studies may also consider submitting an application for the FY11 PCRP Population-Based Research Award; each research project may be submitted to only one award mechanism.

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

1) ***Qualified Collaborator Option:*** This award mechanism strongly supports collaborative research involving basic 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 collaboration 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

collaborator 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 that the success 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).
- 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:*** This award mechanism encourages applications from investigators in the early stages of their careers. The New Investigator Option is designed to allow applicants, 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 in separate groups. 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 applicant to describe how additional investigators will augment the PI's expertise and better address the research question. Applicants may choose to employ both the New Investigator Option and the Qualified Collaborator Option. All applicants for the New Investigator Option must meet specific eligibility criteria as described in Section I.C., Eligibility.

***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 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/.
- 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 for information on current CBPR programs and scientists and communities engaged in health disparity research.
- 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-cancer-research.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 establish and/or maintain interactions with organizations relevant to their proposed studies including 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, The Prostate Net, or other relevant organizations.

## C. Eligibility Information

The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent), unless applying for the New Investigator Option.

***New Investigator Option: To be eligible for this option, the PI must, by the application submission deadline date, have:***

- The freedom to pursue individual aims without formal mentorship, ***and***
- Not previously received a PCRP New Investigator Award; ***and***

- Not previously received a PCRP Health Disparity Research Award-New Investigator Option; ***and***
- Either completed at least 3 years of postdoctoral training or fellowship, ***or*** are within 5 years of having begun first independent faculty position (or equivalent).

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 individual aims without formal mentorship. The PI is required to submit an Eligibility Statement to verify these qualifications. Graduate students and junior postdoctoral fellows (i.e. fellows with less than 3 years postdoctoral training) are not eligible for this award.

- 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 costs amount for the entire period of performance is **$450,000** plus indirect costs. If using the Qualified Collaborator Option, the maximum allowable direct costs amount for the entire period of performance is **$600,000** plus indirect costs.
    - Applications requesting the higher level of funding that do not include a qualified collaborator who meets the specified criteria will have their 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 form. In addition, for this award mechanism, direct costs:

Must be requested for:

- The PI to travel to one 3½-day PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting, which is held to disseminate the results of PCRP-sponsored research.

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
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to $1,800 (or $3,600 for applications that include the Qualified Collaborator Option) per year to attend scientific/technical meetings

***The CDMRP expects to allot approximately $3.6M of the $80M FY11 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 discouraged. The Government reserves the right to 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-11-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 a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

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

- Health Disparity Research Award, ***or***
- Health Disparity Research Award-New Investigator Option, ***or***
- Health Disparity Research Award-Qualified Collaborator Option, ***or***

- Health Disparity Research Award-New Investigator and Qualified Collaborator Options.

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**
- **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.

- **Submit Pre-application – Tab 5**
- **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 (AOR) 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):

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 (10-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 may not 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.
- **Focus Areas and Overarching Challenges:** Briefly describe (a) how the proposed research and training are responsive to at least one of PCRP focus areas and, ***if applicable***, (b) how the proposed research addresses one of the PCRP overarching challenges.

- **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. ***Each component has no page limit unless otherwise noted.***
  - 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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they must be included. 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 Description, 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:
  - ***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.
  - ***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.
  - ***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."

  Describe the proposed research project, including the following elements: Background, Objective/Hypothesis, Study Design and Specific Aims, Impact, and Innovation. 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.

- **Attachment 4: Public Abstract (one-page limit):** Upload as "PublicAbs.pdf."

  Public 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 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.

  ***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 ultimately contribute to the goal of eliminating death and suffering from prostate cancer.

  ***PCRP Overarching Challenges:*** If applicable, describe how the proposed research addresses one of the overarching challenges.

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

  Summarize how the proposed work is innovative. Proposing 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.

3. **Research & Related Senior/Key Person Profile (Expanded) Form:** 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.

### 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 shall 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 Number 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, USAMRMC, based on technical merit, the relevance to the mission of the DOD and CDMRP, and the specific intent of the award mechanism. The highest scoring 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, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

### B. Application Review Criteria

1. **Peer Review:** To determine the 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 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 uniquely 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.
  - ***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 additional investigators included on the research team will appropriately complement the New Investigator's ability to perform 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.

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 CDMRP, 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
   - 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. PIs 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:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Pre-application is not submitted.

### 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, you 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.

### C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY11 PCRP Integration Panel (IP) member is found to be involved in the preapplication 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 FY11 PCRP IP members may be found at http://cdmrp.army.mil/pcrp/panels/panel11.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- 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 and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.

- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The proposed research is or includes a clinical trial.
- 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 US 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, 2012. 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 C, for general information regarding administrative and national policy requirements.

### C. Reporting

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

### D. Award Transfers

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

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.

## VI. AGENCY CONTACTS

### A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements and 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

### 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

***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

| Grants.gov Application Components | Action | Completed |
|---|---|---|
| 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 Public Abstract (PublicAbs.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. | |
| | ***Qualified Collaborator Option only*:** Upload Qualified Collaboration Statement (QualCollab.pdf) as Attachment 8 (if applicable). | |
| | ***New Investigator Option only*:** Upload Eligibility Statement (Eligibility.pdf) as Attachment 9 (if applicable). | |
| 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 form 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. | |