

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Health Disparity Research Award

Funding Opportunity Number: W81XWH-10-PCRP-HDRA

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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 Fiscal Year 1997 (FY97) through FY09 totaled \$970 million (M). The FY10 appropriation is \$80M.

The overall goal of the FY10 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 transition 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.

New for FY10: PCRP Overarching Challenges

The goals of the FY10 program are aimed towards eliminating death and suffering from prostate cancer. Applications for the PCRP Health Disparity Research Award are ***encouraged but not required*** to address at least one of the following PCRP overarching challenges:

- Develop effective treatments for advanced prostate cancer
- Distinguish lethal from indolent disease

PCRP Focus Areas (*revised for FY10*)

Applications for the PCRP Health Disparity Research Award ***must*** address at least one of the following FY10 PCRP focus areas:

Biomarkers: Discovery and validation of biomarkers for the detection, 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 imaging technology for the detection and prognosis of prostate cancer, including progression to systemic disease

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 or molecules for the treatment of prostate cancer.

Tumor Biology: Understanding the heterogeneity and microenvironment for the prognosis and progression of prostate cancer.

B. Award Description

The PCRCP Health Disparity Research Award mechanism was introduced in FY01. Since then, 177 applications have been received, and 45 have been recommended for funding. In FY09, through a Request for Information (RFI), the PCRCP solicited feedback from the prostate cancer research community on critical needs to facilitate prostate cancer health disparity research. This award mechanism has been modified for FY10 in response to the RFI feedback received.

The Health Disparity Research Award supports new ideas that represent innovative approaches to prostate cancer health disparity research with the potential to make an important contribution to eliminating death and suffering from prostate cancer. The Health Disparity Research Award reflects the PCRCP's commitment to resolving disparities in prostate cancer incidence, morbidity, and mortality by funding health disparity-focused projects. Studies proposed for this award mechanism are expected to improve the understanding of, and ultimately eliminate, 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.

Due to this award's emphasis on innovation, presentation 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 Principal Investigator (PI) or member(s) of the collaborating team.

Research involving human subject use is permitted under this funding opportunity, but is restricted to studies without clinical trials. In general, a clinical trial is defined as a prospective study where an intervention (e.g., device, drug, behavioral, surgical procedure, or other) is tested on human subjects for a measurable outcome. Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects data, or human anatomical substances.

The PCRCP seeks Health Disparity Research Award applications from the wide spectrum of basic to clinical research (excluding clinical trials). Applications ***must*** be responsive to at least one of the PCRCP focus areas and, although not required, ***may*** also be responsive to the PCRCP overarching challenges. PIs wishing to apply for funding for population-based studies may also consider submitting an application for the PCRCP Population-Based Research Award; each research project may be submitted to only one award mechanism.

New for FY10! The following components of the Health Disparity Research Award are new for this fiscal year:

1. ***Qualified Collaborator Option:*** The FY10 Health Disparity Research Award strongly supports collaborative research between basic and clinical researchers, between researchers with prostate cancer expertise and those with health disparity expertise, and between 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:*** The FY10 Health Disparity Research 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. Applicants for the New Investigator Option are strongly encouraged to strengthen their applications by including investigators experienced in prostate cancer research and/or 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 for the New Investigator Option are permitted to also use the Qualified Collaborator Option. All applicants for the New Investigator Option must meet specific eligibility criteria as described in Section I.C., Eligibility.
3. ***Health Disparity Research Resources:*** Responses to the FY09 PCRFP RFI identified difficulties in establishing relevant collaborations and obtaining access to relevant study populations as major barriers to prostate cancer health disparity research. Therefore, 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 is supported by the PCRP to conduct prostate cancer health disparity studies. PCaP members and institutions may be found at <http://www.ncla-pcap.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 DOD and other government-funded investigators through DTIC Technical Reports at <http://www.dtic.mil/dtic/>.
- 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.
- 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>

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.

It is the responsibility of the PI to clearly and explicitly articulate how the project addresses the following important aspects of the Health Disparity Research Award:

1. **Research Question:** Applications must clearly describe how the research question is relevant to an area of prostate cancer health disparity such as race and ethnicity, socioeconomic status, access to health care, insurance status, age, geography, and cultural beliefs.
2. **Innovation:** Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. Innovative research may include high-risk approaches to prostate cancer health disparity research. Research that is an incremental advance upon published data is not considered innovative.

3. **Impact:** Research that has high impact will, if successful, 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.
4. **Responsiveness to PCRP focus areas and overarching challenges:** Applications should describe the relevance of the proposed project to at least one of the PCRP focus areas. Relevance to a PCRP overarching challenge, if applicable, should also be described.

C. Eligibility

Applicants must be independent investigators at or above the level of Assistant Professor (or equivalent), unless applying for the New Investigator Option.

To be eligible for the New Investigator Option, applicants must meet the following criteria by the application submission deadline date:

- Must have the freedom to pursue individual aims without formal mentorship, *and*
- Have not previously received a PCRP New Investigator Award; *and*
- Either have 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 they have the freedom to pursue individual aims without formal mentorship. The PI is required to submit an Eligibility Statement to verify these qualifications. Please note that graduate students and junior postdoctoral fellows are not eligible for this award. Refer to General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable funding for the entire period of performance is **\$450,000** in direct costs. If applying for the Qualified Collaborator Option, the maximum allowable funding for the entire period of performance is **\$600,000** in direct costs.
 - Applications requesting the higher level of funding that do not include a qualified collaborator who meets all of the specified criteria will have their budgets reduced as appropriate.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

Within the guidelines provided in the General Application Instructions, funds can cover:

- 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 applications that include the Qualified Collaborator Option) per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

In addition, funding must be requested for the PI to travel to one 3½-day PCRPA IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$4.3M of the \$80M FY10 PCRPA appropriation to fund approximately six 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.

E. Award Administration

Changes in PI are not allowed for the award recipients using the New Investigator Option of this award, except under extenuating circumstances that will be evaluated on a case-by-case basis 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.

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), May 5, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, May 26, 2010**
- **Scientific Peer Review: July/August 2010**
- **Programmatic Review: October 2010**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

III. SUBMISSION PROCESS

Submission is a two-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.

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 eReceipt help desk at help@cdmrp.org or 301-682-5507.

A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the [CDMRP eReceipt system](#) by **5:00 p.m. ET on the deadline**.

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 for additional information on pre-application submission.):

- **Proposal Information – Tab 1**
- **Proposal Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

- **Required Files – Tab 4**
 - **Letter Intent (LOI) Narrative (one-page limit):** Provide a brief description of the research to be conducted. LOI Narratives 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 (not applicable)**

B. Step 2 – Application Components

Applications will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (<http://www.grants.gov/>). Applications must be submitted by **11:59 p.m. ET on the deadline.**

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

1. SF 424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.B., 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 analysis. 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.
- **PCRP Focus Areas and Overarching Challenges:** Describe how the project is responsive to at least one of the PCRP focus areas. If applicable, describe how the project is also responsive to at least 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 all relevant references 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). The inclusion of Internet URLs to references is encouraged.
 - **List of Acronyms and Symbols:** Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
 - **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) (two-page limit per letter):** 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 (two-page limit per letter)
 - ***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 collaborators for the proposed project (if applicable), provide a signed letter 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.”

Technical abstracts should be written using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design including appropriate controls.
- **Innovation:** Briefly describe how the proposed project uses innovation to yield critical discoveries, new avenues of investigation, or major advancements to accelerate prostate cancer health disparity research.
- **Impact:** Summarize how the proposed project will, if successful, 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.
- **Focus Areas and Overarching Challenges:** Summarize how the proposed project addresses at least one of the PCRP focus areas and, if applicable, one of the PCRP overarching challenges.

- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
Public abstracts should be written using the outline below.
 - Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
 - Do not duplicate the technical abstract.
 - 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) (two-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as “Budget.pdf.” Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 8: Impact Statement (one-page limit).** Upload as “Impact.pdf.”
State explicitly how the proposed work will, if successful, 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.
- **Attachment 9: 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 PIs frame the innovative features of their proposals:

- 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 10 (*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 Description. 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 11 (*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 verifying 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.B., 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. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific 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 scientific merit, the overall goals of the program, and 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 may be found at <http://cdmrp.army.mil/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 nondisclosure 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. Review Criteria

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

- **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.
- **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, if successful, will 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.
- **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**
 - Whether the PI meets the appropriate eligibility requirements.
 - 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.

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Responsiveness to Focus Areas and Overarching Challenges**
 - Whether the proposed research project responds to at least one of the PCRP focus areas and, if applicable, one of the PCRP overarching challenges toward the goal of eliminating death and suffering from prostate cancer.
- **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**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations.

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

V. 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Pre-application is not submitted.

B. Modifications

- 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 V-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:

- FY10 PCRP Integration Panel (IP) member(s) 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 FY10 PCRP IP members may be found at <http://cdmrp.army.mil/pcrp/panel10>
- 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 detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The proposed research 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 requested 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.

VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Email: cdmrp.pa@amedd.army.mil

B. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Email: help@cdmrp.org

C. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 800-518-4726
Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. 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 Detailed Budget and Justification (Budget.pdf) as Attachment 6	
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7	
	Upload Impact Statement (Impact.pdf) as Attachment 8	
	Upload Innovation Statement (Innovation.pdf) as Attachment 9	
	<i>Qualified Collaborator Option only:</i> Upload Qualified Collaboration Statement (QualCollab.pdf) as Attachment 10	
	<i>New Investigator Option only:</i> Upload Eligibility Statement (Eligibility.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	
Project/Performance Site Location(s) Form	Complete form as instructed	