# **Program Announcement**

# Department of Defense (DOD) Congressionally Directed Medical Research Programs

# **Prostate Cancer Research Program (PCRP)**

## **Health Disparity Research Award**

Funding Opportunity Number: W81XWH-08-PCRP-HDRA

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#### I. HELPFUL INFORMATION

#### A. Contacts

1. Program announcement, proposal format, or required documentation: To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov basic search using the CFDA Number 12.420. 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

Fax: 301-619-7792

Email: cdmrp.pa@amedd.army.mil

**2. eReceipt system:** Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507

Website: <a href="https://cdmrp.org">https://cdmrp.org</a>

Email: <u>help@cdmrp.org</u>

**3. Grants.gov contacts:** Questions related to submitting applications through the <u>Grants.gov</u> (<a href="http://www.grants.gov/">http://www.grants.gov/</a>) portal should be directed to Grants.gov help desk. Deadlines for proposal submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: <u>support@grants.gov</u>

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the "send me change notification emails" link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.

#### **B.** National Technical Information Service

The technical reference facilities of the National Technical Information Service (<a href="www.ntis.gov">www.ntis.gov</a>) are available for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources should also be consulted to the extent practical for the same purpose.

## C. Commonly Made Mistakes

- Not obtaining or confirming the organization's DUNS number well before the proposal deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting HELP DESKS until just before or after deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline (i.e., pre-application remains in draft status).
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by submission deadline.

## II. FUNDING OPPORTUNITY DESCRIPTION

## A. Program History and Objectives

The PCRP was established in fiscal year 1997 (FY97) to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY07 totaled \$810 million (M). The FY08 appropriation is \$80M.

The overall goal of the FY08 PCRP is to find and fund innovative, high-impact research relevant to the prevention, detection, diagnosis, and/or treatment of human prostate cancer. Specifically, the PCRP seeks to:

Support innovative research by individual investigators in multiple disciplines;

- Sponsor multidisciplinary team science to bring together diverse expertise and approaches that will accelerate the conquest of prostate cancer;
- Fund translational research to promote the bench-to-bedside-to-bench transition between basic and clinical science;
- Foster the next generation of prostate cancer investigators through mentored research and training; and
- Promote research into prostate cancer health disparities, including, but not limited to, race and ethnicity, socioeconomic status, access to health care, insurance status, age, geography, and cultural beliefs.

## **B.** Award Description

The PCRP Health Disparity Research Award mechanism was introduced in FY01. Since then, 95 proposals have been received and 30 have been recommended for funding.

The Health Disparity Research Award reflects the PCRP's commitment to resolving disparities in prostate cancer incidence, morbidity, and mortality by funding health disparity-focused projects by investigators at multiple points in their careers:

- **Transitioning Investigators:** Mentored investigators transitioning into their first independent faculty position and establishing their own independent research programs.
- Early-Career Investigators: Independent investigators in the early stages of their careers.
- **Established Investigators:** Independent investigators at or above the Assistant Professor level or equivalent.

## Appropriate disparity focus areas include, but are not limited to:

- Race and ethnicity,
- Socioeconomic status,
- Access to health care,
- Insurance status,
- Age,
- · Geography, and
- Cultural beliefs.

PIs who do not have either experience in prostate cancer research or a connection to, or effectiveness in working with, an affected population or community are strongly encouraged to include a collaborator (or collaborators) with the appropriate prostate cancer or health disparity research experience. Such experience may include:

• Being a member of the affected population or community with a demonstrated commitment to the affected population or community;

- Having experience working with the affected population or community; or
- Having interactions with or an active membership in organizations such as the Urban League, National Medical Association, National Alliance for Hispanic Health, American Indian Health Care Association, National Rural Health Association, Patient Advocate Foundation National African American Outreach Program, or Prostate Health Education Network (PHEN).

In addition, the proposal must explicitly state how the proposed research is related to a health disparity focus area in prostate cancer.

This award may support research with laboratory animals and human biological substances, as well as research with human subjects that does *not* involve clinical trials. *Clinical trials are not acceptable under this mechanism. PIs wishing to apply for funding for a clinical trial should utilize the Clinical Trial Award mechanism.* Specific information for each category of Health Disparity Research Award appears below. *Each PI may apply in only one category.* 

	Transitioning Investigator	Early-Career Investigator	Established Investigator
Eligibility*:			
Years beyond post-doc fellowship	Less than 3	Less than 6	Must be at or above the level of Assistant Professor or equivalent
Maximum in previous federal or private funding as a PI or co-PI	\$300,000	\$300,000	No maximum
Preliminary data required?	No	No	No
Other personnel required?	Yes – Mentor	Yes – Collaborator	No
Most important aspects	(1) PI (2) Mentor (3) Career Development Program and Environment	(1) Personnel (2) Impact (3) Research Strategy and Feasibility	(1) Innovation (2) Impact (3) Research Strategy and Feasibility

Further details on each award can be found below:

1. Transitioning Investigator: These mentored awards are designed to support investigators who, at the time of submission, either (1) have documentation of receipt of their first independent faculty appointment (or equivalent); or (2) are within 3 years of having started their first independent faculty position (or equivalent). If the first independent faculty position is not started by January 30, 2009, the Government reserves the right to withdraw the award.

The first independent position is defined as the Assistant Professor level or an equivalent faculty position (e.g., Assistant Member, Laboratory Head, Principal Investigator, etc.), at which the candidate is expected to establish his or her own independent research program, prepare applications for additional research funding, and act as a PI on such independent research projects.

These awards will provide investigators committed to prostate cancer health disparity research the opportunity to acquire, in their first independent faculty position, the data and experience needed to compete for traditional awards later in their career. Funds are intended to provide 50% protected time for research.

Important aspects of the Transitioning Investigator Award are:

- **a. PI's qualifications:** The PI must demonstrate strong qualifications for and a commitment to an independent career in prostate cancer health disparity research.
- **b. Mentor:** Submission to this award mechanism as a Transitioning Investigator requires a designated *mentor*, appropriate to the proposal, who has experience in prostate cancer health disparity research as demonstrated by a record of funding and publications. The selected mentor should be well-qualified to significantly contribute to the development of the PI toward a career in prostate cancer health disparity research.
- **c.** Research and career development environment: The PI must describe his or her research project as well as his or her career goals in the body of the proposal. Proposals should either extend the PI's ongoing research related to prostate cancer health disparity or broaden the scope of his or her research to include work relevant to health disparities, under the guidance of a designated mentor with expertise in prostate cancer health disparity research.
- **2. Early-Career Investigator:** These awards are designed to foster independent PIs, in the early stages of their careers, (see <u>Eligibility</u>, below) who have innovative, high-impact ideas or new technologies applicable to prostate cancer health disparities. Funds are intended to provide 50% protected time for research.

Important aspects of the Early-Career Investigator Award are:

- **a. Personnel:** The PI's record of accomplishment will be evaluated regarding his or her potential for contributing to the prostate cancer health disparity research field. The *required collaborator* will be evaluated by his/her experience in prostate cancer health disparity research as demonstrated by a record of funding and publications. The PI and collaborator together will be emphasized in peer review to determine whether their combined background and prostate cancer-related expertise demonstrate the ability to accomplish the proposed work.
- **b. Impact:** Research that has high impact will, if successful, significantly contribute to the goal of reducing prostate cancer health disparity. It is the responsibility of the PI to clearly and explicitly articulate the potential impact the proposed research will have on prostate cancer health disparity.
- **c. Preliminary Data:** To encourage submissions from PIs early in their careers, *proposals are not required to have preliminary data.* Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, these

proposals should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

- **d. Innovation:** Innovative research may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. It is the responsibility of the PI to clearly and explicitly articulate how the proposed research is innovative. Research that is an incremental advance upon published data is not considered innovative, and will not be considered for funding under this mechanism.
- **3. Established Investigator:** These awards support innovative, high-risk/high-gain studies of prostate cancer health disparities from independent investigators at the Assistant Professor level or above (see Eligibility, below).

Important aspects of the Established Investigator Award are:

- **a. Innovation:** Innovative research may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. It is the responsibility of the PI to clearly and explicitly articulate how the proposed research is innovative. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this mechanism.
- **b. Impact:** Research that has high impact will, if successful, significantly contribute to the goal of reducing prostate cancer health disparity. It is the responsibility of the PI to clearly and explicitly articulate the potential impact the proposed research will have on prostate cancer health disparity.
- c. Preliminary Data: Submission of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, these proposals should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

#### C. Eligibility

Eligibility criteria for each category are listed below. *Each PI may apply for only one category of award:* 

## 1. Transitioning Investigator

- Must have a *designated* mentor with experience in prostate cancer health disparity research;
- Must hold a Ph.D. and/or an M.D. degree;
- Must have received no more than \$300,000 in direct costs in aggregate as a PI or co-PI of a federally or privately funded, non-mentored peer reviewed grant (e.g., R01, DOD Idea Development Award) at the time of proposal submission;
- By the time of proposal submission, must either:

- By the time of proposal submission, must either:
  - Have documentation of receipt of his or her first independent faculty appointment (or equivalent); or
  - o Be within 3 years of having started his or her first independent faculty position (or equivalent).

The first independent faculty position is defined as the Assistant Professor level or an equivalent faculty position (e.g., Assistant Member, Laboratory Head, Principal Investigator, etc.), at which the candidate is expected to establish his/her own independent research program, prepare applications for additional research funding, and act as a PI on such independent research projects.

If the independent faculty position is not started by January 30, 2009, the Government reserves the right to withdraw the award.

- **2.** Early-Career Investigator: Independent investigators who, at the time of submission:
  - Are within 6 years of having completed postdoctoral or fellowship training; and
  - Hold a position at the level of Instructor, Assistant Professor, or equivalent; and
  - Have received no more than \$300,000 in direct costs in aggregate as a PI or co-PI of a federally or privately funded, non-mentored peer reviewed grant (e.g. R01, DOD Idea Development Award); and
  - Have acquired sufficient skills and knowledge to function independently; and
  - Have the freedom to pursue individual aims without formal mentorship; and
  - Can provide evidence of institutional support, such as start-up funds by the institution, use of a technician, space, facilities, and resources.

PIs working within a laboratory team are eligible to apply for this award provided that they can demonstrate that they are independent investigators according to the criteria above.

- **3. Established Investigator:** Independent investigators who, at the time of submission:
  - Have access to facilities appropriate for health disparity research;
  - Are at or above the level of Assistant Professor (or equivalent).

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

## D. Funding

Funding for a Health Disparity Research Award can be requested for up to 3 years for each category of PI as indicated below. Indirect costs may be added as appropriate:

	Transitioning Investigator	Early-Career Investigator	Established Investigator
Maximum Funding (Direct Costs)	\$225,000	\$225,000	\$375,000

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

- Salary
- Research supplies
- Equipment
- Clinical costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions

For Transitioning Investigator and Early-Career Investigator PIs, institutional commitment must demonstrate 50% protected time for research. Salary support must be commensurate with level of effort.

In addition, funding must be requested for the PI to travel to the next PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting (tentatively scheduled for 2010).

The CDMRP expects to allot approximately \$3.2M of the \$80M FY08 PCRP appropriation to fund approximately eight Health Disparity Research Award proposals, depending on the quality and number of proposals received. Funding of proposals received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

## E. Award Administration

Changes in PI are not allowed for the Transitioning Investigator and Early-Career Investigator categories of this award.

For Transitioning Investigator Awards, where the PI has changed institutions after proposal submission but prior to assistance agreement award, the submitting institution must agree to relinquish the award so that it can be transferred to the PI's new institution. To avoid this necessity, Transitioning Investigator PIs are encouraged to submit their proposals from the institution providing the faculty appointment.

Refer to the Application Instructions, Appendix 5, for general award administration information.

#### III. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) proposal submission. *Pre-application submission is a required first step*.

Pre-application Submission Deadline: 5:00 p.m. Eastern time, June 18, 2008
 Confidential Letters of Recommendation 5:00 p.m. Eastern time, July 2, 2008

• Proposal Submission Deadline: 11:59 p.m. Eastern time, July 2, 2008

Peer Review: September 2008
 Programmatic Review: November 2008

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009.

#### IV. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the <u>CDMRP eReceipt system</u> (<a href="https://cdmrp.org/">https://cdmrp.org/</a>) and (2) a proposal submission through <u>Grants.gov</u> (<a href="https://www.grants.gov/">https://www.grants.gov/</a>).

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

#### A. Step 1 – Pre-Application Components and Submission

The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the <a href="CDMRP eReceipt system">CDMRP eReceipt system</a> by 5:00 p.m. Eastern time on the pre-application deadline. Refer to the Application Instructions for detailed information

- 1. Proposal Information
- 2. Proposal Contacts
- 3. Collaborators and Conflicts of Interest
- 4. Letter of Intent Narrative
- 5. List of Individuals Providing Confidential Letters of Recommendation (for Transitioning Investigator PIs only)

#### B. Step 2 – Proposal Components and Submission

**Proposal submission will not be accepted unless a pre-application was submitted by the pre-application deadline.** Proposals must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (<a href="www.grants.gov">www.grants.gov</a>). No paper copies will be accepted. Transitioning Investigator PIs are encouraged to submit their proposals from the institution providing the faculty appointment.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in <a href="www.grants.gov">www.grants.gov</a> for the US Army Medical Research Acquisition Activity program announcement. In addition to the specific instructions below, please refer to the Application Instructions for detailed requirements of each component.

The package includes:

## 1. SF-424 (R&R) Application for Federal Assistance Form

#### 2. Attachments Form

- Attachment 1: Project Narrative (10-page limit)
  - Transitioning Investigator

Describe the proposed project in detail using the outline below. *Preliminary data are not required but may be included.* 

**PI's Career Goals:** Describe the PI's career goals in prostate cancer health disparity research and how the proposed research and career development experience will promote an independent career in this area. Discuss the PI's career plans after the completion of this award.

**Research Project:** Describe the proposed project, including background, hypothesis/rationale/purpose, objectives, and methods. Discuss the relevance of this research to prostate cancer health disparities. *This award may not be used to conduct clinical trials.* 

Career Development Program: Describe the career development program, which may include conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Describe the mentor's background and experience in prostate cancer health disparity research and discuss how the mentor will assist the PI in developing his or her career as an independent prostate cancer health disparity researcher. Explain how the career development program is supported by the environment; this should include a description of ongoing prostate cancer health disparity research at the institution. Include information on collaborations with other investigators.

**Integration of Career Development and Research:** Describe how the career development and research programs are integrated and how they will contribute to preparing the PI for an independent career in prostate cancer health disparity research.

**Connection to Community:** Explicitly demonstrate how the proposed research is related to a health disparity focus area within an affected population or community.

## o Early-Career Investigator

Describe the proposed project in detail using the outline below. *Preliminary data are not required but may be included.* 

**Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this proposal.

**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 proposal is part of a larger study, present only tasks that the DOD award would fund.

**Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Explain how the PI will have access to the appropriate population. 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.* 

**Collaborator:** Name the required collaborator and describe how he or she will support the PI and project. The PI and collaborator together will be emphasized in peer review to determine whether their combined background and prostate cancer-related expertise demonstrate the ability to accomplish the proposed work.

**Connection to Community:** Explicitly demonstrate how the proposed research is related to a health disparity focus area within an affected population or community.

## Established Investigator

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.* 

**Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this proposal.

**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 proposal is part of a larger study, present only tasks that the DOD award would fund.

**Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Explain how the PI will have access to the appropriate population. 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.* 

**Connection to Community:** Explicitly demonstrate how the proposed research is related to a health disparity focus area within an affected population or community.

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - o Publications and/or Patent Abstracts (five-document limit)
  - Letters of Institutional Support

Provide a letter(s) of institutional support, signed by the Department Chair or appropriate institutional official, that reflects the laboratory space, equipment, and other resources available for this project. The letter(s) should indicate the level of institutional commitment to fostering the PI's career, as reflected by (1) the extent to which the PI will be relieved of clinical or other responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) opportunities for critical professional interaction with senior colleagues with established research careers. For Transitioning Investigator and Early-Career Investigator PIs, this letter must demonstrate a commitment to allow at least 50% protected time for research. *If* the PI has not started his or her faculty appointment, the start date must be included in the letter.

• Letter(s) 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 (e.g., the Urban League, National Medical Association, National Alliance for Hispanic Health, American Indian Health Care Association, National Rural Health Association, Patient Advocate Foundation National African American Outreach Program, or Prostate Health Education Network (PHEN)), a letter of support from each organization is encouraged. Such letter(s) of support should explain the nature of the PI's relationship to the organization, the involvement of the PI with the affected population or community, the importance of the project within the affected population or community, any long-term application of the project to the affected population

or community, and the PI's commitment to the affected population or community and health disparity.

- Letters of Collaboration (if applicable)
  - Required (for Early-Career Investigator PIs only): Provide a signed letter from the required collaborator(s) that describes how he or she will support the PI and the project.
  - **If applicable:** Provide a signed letter from each additional collaborating individual or institution that will demonstrate that the PI has the resources necessary for the proposed work. Established Investigator PIs who do not have experience in prostate cancer research or a connection to, or effectiveness in working with, an affected population or community are strongly encouraged to include a collaborator (or collaborators) with the appropriate prostate cancer or health disparity research experience.
- o Documentation of Rights to Project (for Transitioning Investigator PIs only, if applicable).
  - For Transitioning Investigator PIs who are completing postdoctoral fellowships (or equivalent) at the time of submission and plan to continue their current projects during the tenure of this award, provide a letter from the laboratory director (or equivalent) affirming that the PI has full rights to the project and may continue it at either the same or another institution after beginning the faculty appointment.
- o Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical and Public Abstracts
- Attachment 4: Statement of Work
- Attachment 5: Impact Statement
  - State explicitly how the proposed work will, if successful, have an impact on prostate cancer health disparity research or patient care. Describe how the expected results of the proposal will contribute to the goal of reducing prostate cancer disparities.
- Attachment 6: Innovation Statement (Early-Career and Established Investigator PIs only)
  - Summarize how the proposal is innovative. The following examples of ways in which proposals 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 question in prostate cancer health disparity research.

 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.

# Investigating the next logical step or incremental advancement on published data is not considered innovative.

- Attachment 7: Statement of Eligibility (Transitioning Investigator and Early-Career Investigator PIs only)
- Attachment 8: Federal Agency Financial Plan (if applicable)

## 3. Research & Related Senior/Key Person Profile (Expanded)

- PI Biographical Sketch
- PI Current/Pending Support
- Key Personnel Biographical Sketches
  - For the Transitioning Investigator Award, a biographical sketch of the PI's mentor is required.
- Key Personnel Current/Pending Support
   For the Transitioning Investigator Award, Current/Pending Support for the PI's mentor is required.

## 4. Research & Related Budget Form

- Budget Justification
- 5. Research & Related Project/Performance Site Location(s) Form
- 6. R&R Subaward Budget Attachment(s) Form (if applicable)

Confidential Letters of Recommendation (required for Transitioning Investigator PIs only; two-page limit per letter): In addition to the completed Grants.gov application package of forms and attachments, Transitioning Investigator proposals also require the submission of three confidential letters of recommendation by the individuals designated during the pre-application process. The PI should monitor whether the letters have been received; however, the PI is not permitted or able to view these letters. If confidential letters of recommendation cannot be submitted by the individuals named in the pre-application, the PI must contact the CDMRP eReceipt help desk at help@cdmrp.org or 301-682-5507.

The confidential letters should include the following:

• A confidential letter of recommendation from the mentor, describing his or her commitment to the PI's career development and mentorship in prostate cancer health disparity research. The mentor should address the following in his or her confidential letter of recommendation:

- o The PI's potential to become a prostate cancer health disparity researcher.
- The mentor's proposed interactions with the PI during the PI's first faculty appointment.
- The research and career development environment, including ongoing prostate cancer health disparity research, at the institution where the PI has his or her faculty appointment and how this environment will promote the development of the PI as an independent prostate cancer health disparity researcher.
- o Research being performed with the mentor's guidance and how this research is relevant to prostate cancer health disparities.
- o How the mentor will assist the PI in developing an independent career in prostate cancer health disparity research.
- o The mentor's history of supporting the development of investigators at the early stages of their careers.
- o The resources available to adequately support the PI's project (specific details on existing support should be covered in the Existing/Pending Support section).
- Two additional confidential letters of recommendation.

Refer to the Application Instructions for additional information regarding submission of the confidential letters of recommendation.

#### V. INFORMATION FOR PROPOSAL REVIEW

## A. Proposal Review and Selection Overview

All proposals are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program. Additional information about the two-tier review process used by the CDMRP may be found at <a href="http://cdmrp.army.mil/fundingprocess">http://cdmrp.army.mil/fundingprocess</a>

The peer review and program review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that proposal 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 correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation (e.g., Impact Statement or Statement of Eligibility).

#### B. Review Criteria

#### 1. Peer Review

**a.** Transitioning Investigator: All Transitioning Investigator proposals will be evaluated according to the following criteria, which are listed in decreasing order of importance.

## • Principal Investigator

- How the PI's achievements (as reflected by academic performance, awards, honors, and previous funding) indicate a potential for success in prostate cancer health disparity research.
- How confidential letters of recommendation from the mentor and others support the PI's potential for a productive career in prostate cancer health disparity research.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- To what extent the PI demonstrates the potential to become a successful independent prostate cancer health disparity researcher.
- How the PI's stated career goals demonstrate a commitment to pursuing a career as a prostate cancer health disparity researcher.
- o The extent to which the PI demonstrates a connection to, or effectiveness in working with, the affected populations or communities.
- o Whether the PI meets the appropriate eligibility requirements.

#### Mentor

- o How the mentor's achievements in preparing investigators for careers in health disparity research indicate the potential for successful mentorship of the PI.
- How the mentor's research experience, research program, committed resources, and level of effort are appropriate for the proposed project.
- Whether the quality of the proposal suggests that the mentor provided appropriate guidance.
- o The extent to which the mentor demonstrates a connection to, or effectiveness in working with, the affected populations or communities.

## • Career Development Program and Environment

- How well the PI has outlined an individualized career development program that augments his or her expertise.
- o How well the career development program will prepare the PI for an independent career in prostate cancer health disparity research.

- o How well the career development program addresses an issue related to prostate cancer health disparities.
- How the scientific environment is appropriate for the proposed career development activities, including critical professional interaction with established senior research colleagues.
- o Whether there is a clear institutional commitment to allow 50% protected time for research.
- o How the quality and extent of other institutional support are appropriate.

## Research Strategy and Feasibility

- O How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.
- o How well the hypotheses or objectives, aims, experimental design, methods, and analysis are developed.
- o Whether the research requirements are supported adequately by the scientific environment, necessary resources, and any collaborative arrangements proposed.
- How well the research project will allow the PI to develop the expertise needed to advance an independent career in prostate cancer health disparity research.
- How well the PI acknowledges potential problems and addresses alternative approaches.

#### Impact

- o How well the proposed research addresses an issue of health disparity in prostate cancer in the affected population or community.
- The extent to which the project, if successful, could make an original and significant contribution to the goal of decreasing prostate cancer health disparity.

#### Budget

- o How the budget is appropriate for the proposed research.
- **b.** Early-Career Investigator: All Early-Career Investigator proposals will be evaluated according to the following criteria, which are listed in decreasing order of importance.

## Personnel

- Whether the PI meets the eligibility requirements.
- How the PI's record of accomplishment demonstrates his or her potential for contributing to the field of prostate cancer health disparity research and completing the proposed work.
- The extent to which the research team demonstrates a connection to, or effectiveness in working with, the affected populations or communities.

- How the PI and collaborator's background and prostate cancer-related expertise are appropriate with respect to their ability to perform the proposed work.
- o To what degree the levels of effort are appropriate for successful conduct of the proposed work.

## Impact

- o How well the proposed research addresses an issue of health disparity in prostate cancer in the affected population or community.
- o The extent to which the project, if successful, could make an original and significant contribution to the goal of decreasing prostate cancer health disparity.
- o How the potential gain justifies the perceived risk.

## • Research Strategy and Feasibility

- How the scientific rationale supports the project and its feasibility as
  demonstrated by a critical review and analysis of the literature, prostate cancerrelevant 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.

#### Innovation

- o How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- How the proposed research represents more than an incremental advance upon published data.

#### Environment

- Whether there is a clear institutional commitment to allow 50% protected time for research.
- o How the scientific environment is appropriate for the proposed research.
- How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- o How the quality and extent of other institutional support are appropriate.

#### Budget

• How the budget is appropriate for the proposed research.

**c. Established Investigator:** All Established Investigator proposals will be evaluated according to the following criteria, which are listed in decreasing order of importance.

#### Innovation

- O How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- How the proposed research represents more than an incremental advance upon published data.

## Impact

- o How well the proposed research addresses an issue of health disparity in prostate cancer in the affected population or community.
- o The extent to which the project, if successful, could make an original and significant contribution to the goal of decreasing prostate cancer health disparity.
- o How the potential gain justifies the perceived risk.

## Research Strategy and Feasibility

- How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancerrelevant preliminary data, and/or logical reasoning.
- o 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

- o The extent to which the research team demonstrates a connection to, or effectiveness in working with, the affected populations or communities.
- o How the research team's background and prostate cancer-related expertise are appropriate with respect to its ability to perform the proposed work.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- o Whether the PI meets the eligibility requirements.

#### • Environment

- o How the scientific environment is appropriate for the proposed research.
- How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- o How the quality and extent of other institutional support are appropriate.

## Budget

- o How the budget is appropriate for the proposed research.
- **2. Programmatic Review:** Criteria used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio include:
  - Ratings and evaluations of the peer reviewers,
  - Programmatic relevance,
  - Relative impact,
  - Relative innovation (Early-Career Investigator and Established Investigator Awards only),
  - Program portfolio balance, and
  - Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, USAMRMC.

#### VI. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in preapplication or proposal rejection. **Pre-applications or proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively rejected.** 

The following will result in administrative rejection of the entire proposal:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Budget and/or budget justification are missing.
- FY08 IP members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY08 IP members may be found at <a href="http://cdmrp.army.mil/research">http://cdmrp.army.mil/research</a>

For any other sections of the pre-application or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

Proposals that appear to include plagiarized information will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform the investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.