

Program Announcement

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Prostate Cancer Research Program (PCRP)

New Investigator Award

Funding Opportunity Number: W81XWH-08-PCRP-NIA

Table of Contents

I. Helpful Information.....	2
A. Contacts	2
B. National Technical Information Service	3
C. Commonly Made Mistakes	3
II. Funding Opportunity Description.....	3
A. Program History and Objectives	3
B. Award Description.....	4
C. Eligibility.....	5
D. Funding.....	5
E. Award Administration.....	6
III. Timeline for Submission and Review	6
IV. Submission Process	6
A. Step 1 – Pre-Application Components and Submission.....	6
B. Step 2 – Proposal Components and Submission	7
V. Information for Proposal Review	9
A. Proposal Review and Selection Overview	9
B. Review Criteria.....	10
VI. Compliance Guidelines.....	11

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: <https://cdmrp.org>

Email: help@cdmrp.org

3. Grants.gov contacts: Questions related to submitting applications through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) 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: support@grants.gov

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 (www.ntis.gov) 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 submission 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 PCRCP New Investigator Award mechanism was introduced in FY99. Since then, 1,678 proposals have been received and 365 have been recommended for funding.

The New Investigator Award supports independent PIs in the early stages of their careers. The PCRCP seeks PIs who have innovative, high-impact ideas or new technologies applicable to prostate cancer research, prevention, detection, diagnosis, or treatment. The PCRCP seeks proposals from all areas of basic, preclinical, behavioral, and epidemiological research. *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.*

Important aspects of the New Investigator Award are as follows:

- 1. Personnel:** The PI and collaborator are emphasized in this award. The PI's record of accomplishment will be evaluated regarding his or her potential for contributing to the prostate cancer research field. 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.
- 2. 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. Impact:** Research that has high impact will, if successful, significantly advance current methods and concepts for the prevention, detection, diagnosis, or treatment of human prostate cancer. It is the responsibility of the PI to clearly and explicitly articulate the potential impact the proposed research will have on human prostate cancer.
- 4. Collaborator:** Submission to this award mechanism requires a *collaborator* (or collaborators), appropriate to the proposal, who has experience in prostate cancer research, as demonstrated by a record of funding and publications in prostate cancer research.

5. 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.

C. Eligibility

PIs must be independent investigators. An independent investigator eligible for this award is defined as an individual who, at the time of submission:

- Is within 6 years of having completed postdoctoral or fellowship training; and
- Holds a position at the level of Instructor, Assistant Professor, or equivalent; and
- **NEW FOR FY08:** Has 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
- Has acquired sufficient skills and knowledge to function independently; and
- Has the freedom to pursue individual aims without formal mentorship; and
- Can provide evidence of institutional support, such as start-up funds provided by the institution and/or 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.

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

D. Funding

Funding for a New Investigator Award can be requested for up to \$225,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

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

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

The CDMRP expects to allot approximately \$7.8M of the \$80M FY08 PCRP appropriation to fund approximately 23 New Investigator 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

A change in PI is not allowed for the New Investigator Award mechanism.

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, May 22, 2008
- **Proposal Submission Deadline:** 11:59 p.m. Eastern time, June 12, 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 [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

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 [CDMRP eReceipt system](https://cdmrp.org/) 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

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 through Grants.gov (www.grants.gov). No paper copies will be accepted.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov 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)

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. 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.

- Attachment 2: Supporting Documentation
 - References Cited
 - Acronyms and Symbol Definitions
 - Facilities & Other Resources
 - Description of Existing Equipment
 - Publications and/or Patent Abstracts (five-document limit)
 - Letters of Institutional Support
 - Letters of Collaboration
 - **Required:** 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.
 - 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 human prostate cancer and how the expected results of the proposal will contribute to the goals of conquering prostate cancer and advancing research on the prevention, detection, diagnosis, or treatment of the disease.

- Attachment 6: Innovation Statement

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 research question.
 - 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
- 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
- Key Personnel Current/Pending Support

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)

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 <http://cdmrp.army.mil/fundingprocess>

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, Innovation Statement, or Statement of Eligibility).

B. Review Criteria

1. Peer Review: All proposals will be evaluated according to the following criteria. Of these, Personnel, Innovation, and Impact are equally the most important, with the remaining criteria 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 prostate cancer research field and completing the proposed work.
 - How the PI's and collaborator's background and prostate cancer-related expertise are appropriate with respect to their ability to perform the proposed work.
 - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- **Innovation**
 - 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**
 - How the project will, if successful, make an original and significant contribution to the goals of conquering human prostate cancer and advancing research on the prevention, detection, diagnosis, or treatment of the disease.
 - 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 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.
- **Environment**
 - How the scientific environment is appropriate for the proposed research.
 - How the research requirements are supported by the availability of and

accessibility to facilities and resources (including collaborative arrangements).

- How the quality and extent of institutional support are appropriate.

- **Budget**

- 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 innovation and impact,
- 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 <http://cdmrp.army.mil/research>

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.