

Program Announcement

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Prostate Cancer Research Program (PCRP)

Population-Based Idea Development Award

Funding Opportunity Number: W81XWH-09-PCRP-PBIDA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Prostate Cancer Research Program (PCRP) was established in fiscal year 1997 (FY97) to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY08 totaled \$890 million (M). The FY09 appropriation is \$80M.

The overall goal of the FY09 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 conquering 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;
- 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; and
- Promote research on patient survivorship, life extension, and quality of life.

FY09 PCRP Focus Areas (*New*)

Imaging: Development of new imaging technology for the detection, prognosis, and treatment of prostate cancer.

Biomarkers: Discovery and validation of biomarkers for the detection, prognosis, and progression of prostate cancer, including determination of therapeutic response.

Therapy: Identification of new targets, pathways, and therapeutic modalities or molecules for the treatment of prostate cancer.

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

Tumor Biology: Understanding the etiology of prostate cancer, including heterogeneity and microenvironment as it relates to initiation, progression and prognosis.

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

Applications for the PCRP Population-Based Idea Development Award must address one or more of the focus areas and have a direct relevance to prostate cancer prevention, detection, diagnosis, and/or treatment. Applications will be rated on their responsiveness to the FY09 PCRP focus areas.

B. Award Description

The PCRP Population-Based Idea Development Award mechanism supports innovative high-impact approaches to prostate cancer research that will contribute significantly to the prevention, detection, diagnosis, and/or treatment of prostate cancer or greatly enhance the quality of life for prostate cancer patients. The overall goal of this award is to generate unique information and/or tools that can only be achieved from the perspective of population statistics.

The PCRP seeks applications from all areas of population-based studies including but not limited to population genomics, meta-analysis, prospective and/or retrospective analyses, diet, exercise, survival, population surveillance, etc., with specific relevance to prostate cancer, that are responsive to one or more of the FY09 PCRP focus areas.

NOTE: *Clinical trials are not allowed under this mechanism.* Refer to the Application Instructions and General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research.

It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate how the project addresses the following important aspects of the Population-Based Idea Development Award:

- 1. Innovation:** Innovative research may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. This may include high-risk approaches to prostate cancer provided that there is potential for significant impact. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this mechanism.
- 2. Impact:** Research that has high impact will, if successful, significantly advance current methods and concepts for the prevention, detection, diagnosis, or treatment of prostate cancer in humans.
- 3. Responsiveness to FY09 PCRP focus areas:** The relevance of the research problem to one or more of the focus areas.
- 4. Preliminary Data:** *Submission 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.* Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, applications 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

To be eligible for this award, the PI must be:

- An independent investigator with access to appropriate research facilities, and
- At or above the level of an Assistant Professor (or equivalent).

Refer to Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 4 years.
- The maximum allowable funding for the entire period of performance is **\$600,000** in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 4-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 institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical research costs (Clinical trials are not supported)
- Travel between collaborating institutions
- Travel to scientific/technical meetings

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

The CDMRP expects to allot approximately \$2.9M of the \$80M FY09 PCRIP appropriation to fund approximately three Population-Based Idea Development Award applications, depending on the quality and number received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

E. Award Administration

Refer to the Application Instructions and General Information, Appendix 5, for general award information on changes in award personnel or institution.

II. TIMELINE FOR SUBMISSION AND REVIEW

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

Pre-application Submission Deadline:	April 29, 2009, 5:00 p.m. Eastern Time
Application Submission Deadline:	May 20, 2009, 11:59 p.m. Eastern time
Scientific Peer Review:	July/August 2009
Programmatic Review:	October 2009

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. 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) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at: help@cdmrp.org or 301-682-5507.

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 applications.

A. Step 1 – Pre-Application Components and Submission

Pre-application submission is the required first step. 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 deadline date*. In addition to award-specific information provided below, refer to the Application Instructions and General Information for detailed information on pre-application components and submission.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2 – Application Components and Submission

Applications will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information 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. ***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 relevant literature citations. 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 the DOD 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. Describe the statistical plan for the research proposed. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples, including ethical and regulatory considerations. ***This award may not be used to conduct clinical trials.***
- 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 (if applicable)

Provide a signed letter from each collaborating individual or institution that will demonstrate that the PI has the resources necessary for the proposed work, including but not limited to:

1. Availability of and access to high quality samples, data sets or databases that are necessary for successful completion of the project.
2. Availability of and access to appropriate prostate cancer patient populations and/or families.

- Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract
- Attachment 4: Public Abstract
- Attachment 5: Statement of Work (SOW)
- Attachment 6: Detailed Budget and Justification
- Attachment 7: 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 project will contribute to the goals of conquering prostate cancer and advancing research on the prevention, detection, diagnosis, or treatment of the disease.

- Attachment 8: Innovation Statement

Summarize how the proposed work is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative.

Although not all inclusive, the following examples are ways in which the proposed work may be innovative and are intended to help PIs frame the innovative features:

- 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 preventing, detecting, diagnosing, 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 9: Focus Area Statement

Describe how the proposed research addresses one or more of the FY09 PCRP focus areas.

- Attachment 10: Federal Agency Financial Plan (if applicable)
- Attachments 11-15: Subaward Detailed Budget and Justification (if applicable)

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

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
- Key Personnel Current/Pending Support

4. Research & Related Project/Performance Site Location(s) Form

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 submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. 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 programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application 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 institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions 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).

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

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria. Of these, 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 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, if successful, could 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.
- **Research Strategy and Feasibility**
 - How well the scientific rationale supports the research 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 and integrated into the project.
 - The feasibility of accruing a statistically significant number of patients/volunteers, biological samples, etc.
 - Whether there is documented availability of and access to high quality samples, data sets or databases that are necessary for successful completion of the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Statistical Plan**
 - Whether an appropriate statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
 - The consistency of the data analysis plan with the study objectives.
- **Responsiveness to Focus Area(s)**
 - How well the proposed research project responds to one or more of the FY09 PCRP focus areas toward the goal of advancing prostate cancer research.

- **Personnel**
 - Whether the PI meets the eligibility requirements for this mechanism.
 - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
 - How the research team's record of accomplishment and prostate cancer related expertise demonstrates his/her ability to accomplish the proposed work.

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

- **Ethics and/or Regulatory Issues**
 - How the ethical considerations, information privacy, assessment of risks and benefits of participation will be addressed (if applicable).
 - The plans for data acquisition and storage.
- **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 for the proposed research.
 - Whether the plans to resolve intellectual and material property issues among participating institutions are appropriate (if applicable).
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.
- **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 that maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative innovation, impact, and responsiveness to FY09 PCRP focus areas
- Program portfolio balance

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.

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).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- *NEW for FY09:* Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at <http://cdmrp.army.mil/pcrp/panel09>
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.

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 USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the 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

B. 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

C. Grants.gov contacts: Questions related to application submission through the [Grants.gov](http://www.grants.gov) ([http://www.grants.gov/](http://www.grants.gov)) portal should be directed to the Grants.gov help desk. Deadlines for application submission are 11:59 p.m. Eastern time on the deadline date. Please note that the CDMRP help desk is unable 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 PIs of changes made to this Program Announcement/Funding Opportunity and/or Application Package ONLY if the PI subscribes to the mailing list by clicking on the “send me change notification emails” link 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.