# Program Announcement

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

**Prostate Cancer Research Program (PCRP)**

**Physician Research Training Award**

**Funding Opportunity Number: W81XWH-09-PCRP-PRTA**

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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 Physician Research Training 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 Physician Research Training Award was introduced in FY03. Since then, 93 applications have been received and 40 have been recommended for funding.

The Physician Research Training Award supports a mentored training experience to prepare physicians with clinical duties and/or responsibilities for a productive career in prostate cancer research. The PI must be in the last year of an accredited medical residency or medical fellowship program, or within the first 3 years following his or her appointment as an Instructor, Assistant Professor, or equivalent. A training program appropriate to the area of study, which may include coursework and seminars, that will provide the PI with experience in key areas such as statistics, bioethics, and/or relevant basic science disciplines, must be part of the application. This award requires the involvement of a designated mentor with an established research program in prostate cancer.

Funds from this award are intended to provide aggressive protection, at least 40%, of the PI's time for research. The PI must demonstrate a commitment to a career in prostate cancer research and clinical practice. In addition, up to 50% of a key support person's salary may be provided by this award. Up to $10,000 in funds per year from this award may be used for research supplies and equipment. These funds may be used for research with laboratory animals and human biological substances, as well as research with human subjects that does ***not*** involve clinical trials. PIs may participate in clinical trials as part of their training for this award, but funding for the clinical trials must come from a source other than this award.

The PCRP seeks applications from all areas of basic, preclinical, behavioral, and epidemiological research, that are responsive to one or more of the FY09 PCRP focus areas.

## C. Eligibility

To be eligible for this award the PI must be a physician with clinical duties and/or responsibilities who is either:

- In the last year of an accredited medical residency or medical fellowship program, or
- Within 3 years of having received his or her appointment as an Instructor, Assistant Professor, or equivalent.

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

## D. Funding

- The minimum period of performance is 3 years, and the maximum is 5 years.
- The maximum allowable funding for the entire period of performance is **$130,000 per year** in direct costs.
- Regardless of the period of performance proposed, the budget may not exceed the maximum direct costs. In addition to the direct costs, indirect costs will not exceed 8% of the direct costs for these applications. The maximum indirect cost rate of 8% will be applied to the Modified Total Direct Costs in accordance with the institution's negotiated rate agreement.

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

- Salary support for the PI
- Reductions in institutionally obligated clinical time
- Up to 50% of a key support person's salary (e.g., laboratory technician, research nurse, or data manager)
- Up to $10,000 per year for research supplies and equipment
- Travel between collaborating institutions
- Travel to scientific/technical meetings

Institutional commitment must demonstrate that the salary support requested by the PI provides at least 40% protection of the PI's time for research.

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

***The CDMRP expects to allot approximately $3.5M of the $80M FY09 PCRP appropriation to fund approximately 5 Physician Research Training 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

A change in PI is not allowed for the Physician Research Training Award mechanism, except under extreme circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

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***.

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| **Pre-application Submission Deadline:** | **April 29, 2009, 5:00 p.m. Eastern time** |
| **Confidential Letter of Support:** | **May 20, 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/), and (2) an application submission through 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 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
- Contact Information for Confidential Letter of Support

## 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.***

     - **PI's Career Goals:** Describe the PI's career goals as a researcher and clinician and how the proposed training will promote his or her career in prostate cancer and patient care. Discuss the PI's career plans after the completion of this award.
     - **Training Program:** Describe the training program, which may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Provide a timeline for the training program. Describe the mentor's background and experience in prostate cancer research and discuss how the mentor will assist the PI in developing his or her career. Explain how the training program is supported by the training environment; this should include a description of ongoing prostate cancer research at the institution. Include information on training or collaborations with other investigators.
     - **Research Project:** Describe the proposed project, including background, hypothesis/rationale/purpose, objectives, and methods. Presentation of preliminary data is not required. However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive. Discuss the relevance of this research to prostate cancer. ***This award may not be used to conduct clinical trials.***

- **Integration of Training and Research:** Describe how the training and research programs are integrated and how they will contribute to preparing the PI for a career in prostate cancer research and patient care.

- 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

    The letter(s) should indicate the level of institutional commitment to fostering the PI's research and clinical 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 establish research careers. The letter(s) must demonstrate a commitment to allow at least a 40% effort on the project by the PI.
  - Letters of Collaboration (if applicable)
  - Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract

  Both the training program and the research project should be emphasized.
- Attachment 4: Public Abstract

  Both the training program and the research project should be emphasized.
- 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: Focus Area(s) Statement

  Describe how the proposed research addresses one or more of the FY09 PCRP focus areas.
- Attachment 9: Statement of Eligibility
- 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)

     A biographical sketch of the PI's mentor is required.
   - Key Personnel Current/Pending Support

     Current/Pending Support for the PI's mentor is required.

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

**Confidential Letter of Support (two-page limit recommended):** In addition to the completed Grants.gov application package of forms and attachments, Physician Research Training Award applications also require the submission of a confidential letter of support by the mentor designated during the pre-application process. The PI should monitor whether the letter has been received; however, the PI is not permitted or able to view this letter. If the confidential letter of support cannot be submitted by the individual named in the pre-application, the PI must contact the CDMRP eReceipt help desk for assistance at help@cdmrp.org or 301-682-5507.

The confidential letter of support must describe the mentor's commitment to the training, career development, and mentorship of the PI and should address the following:

- The PI's potential to become a prostate cancer researcher;
- The mentor's proposed interactions with the PI during the PI's training;
- The training environment, including ongoing prostate cancer research, at the institution and how this environment will promote the development of the PI as a prostate cancer researcher;
- The research training program in which the PI will participate including descriptions of coursework, experience with laboratory techniques, conferences, and journal clubs;
- Research being performed under the mentor's direction and how this research is relevant to prostate cancer;
- How the mentor will assist in training the PI for a career in prostate cancer research;
- The mentor's history of training postdoctoral fellows, residents, and fellows;
- The resources available to adequately support the PI's project (specific details on existing support should be covered in the Existing/Pending Support section); and
- The degree to which the PI participated in idea development and application preparation, and the degree to which the PI will participate in the execution of the application if funded.

Refer to the Application Instructions and General Information for additional information regarding submission of the confidential letter of support.

## 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, Principal Investigator, Mentor, and Training Program and Environment are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Principal Investigator**
  - Whether the PI meets the appropriate eligibility requirements.
  - How the PI's achievements (as reflected by academic performance, awards, honors, and previous funding) indicate a potential for successful training in prostate cancer research.

- How the mentor's letter of support provides evidence for the PI's potential for a productive career in prostate cancer 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 prostate cancer researcher and clinician.
- How the PI's stated career goals demonstrate a commitment to pursuing a career as a prostate cancer researcher and clinician.

- **Mentor**
  - How the mentor's training achievements, as reflected by his or her previous trainees' career achievements and areas of interest, indicate the potential for successful training of the PI in prostate cancer research.
  - How the mentor's research experience, research program, committed resources, and level of effort are appropriate for the proposed training program.
  - Whether the quality of the application suggests that the mentor provided appropriate guidance in its preparation.
- **Training Program and Environment**
  - How well the training program addresses an issue related to prostate cancer research or clinical medicine.
  - How well the PI has outlined an individualized training program that augments his or her expertise.
  - How well the training will prepare the PI for an independent career in prostate cancer research and clinical medicine.
  - How the scientific environment is appropriate for the proposed training activities, including critical professional interaction with established senior research colleagues.
  - Whether there is a clear institutional commitment to allow at least 40% protection of the PI's time for research.
  - How the quality and extent of other institutional support are appropriate.
- **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 Project, Strategy, and Feasibility**
  - How the research project is appropriate to prepare the PI for a successful career in prostate cancer research and clinical medicine.

- Whether the research requirements are supported adequately by the scientific environment, necessary resources, and any collaborative arrangements proposed.
- 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.

- **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.

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

- **Budget**
  - How 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 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 by 5:00 p.m. Eastern time on the second full business day following the date 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/) 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.***