Program Announcement

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Prostate Cancer Research Program (PCRP)

Prostate Cancer Training Award

Funding Opportunity Number: W81XWH-09-PCRP-PCTA

Table of Contents

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 the 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 Prostate Cancer Training Award must address one or more of the FY09 PCRP 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 Prostate Cancer Training Award mechanism was introduced in FY06. Since then, 467 applications have been received and 158 have been recommended for funding.

The Prostate Cancer Training Award supports training opportunities focused on prostate cancer research or patient care for individuals in the early stages of their careers. The focus of these awards is on the PI, the mentor, and the training program and environment. These awards primarily provide salary support for the PI and require the active involvement of a mentor who is an established prostate cancer researcher, as evidenced by a demonstrated record of funding and publications in prostate cancer research. All Prostate Cancer Training Award proposals are to be written with appropriate direction from the mentor and signed by the trainee as the PI and author of the proposal. PIs may apply for predoctoral and postdoctoral traineeships through this award mechanism. 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.

It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate how the project addresses the following important aspect of the Prostate Cancer Training Award:

1. Principal Investigator and Mentor: The PI must demonstrate strong qualifications for and a commitment to pursuing a career as a prostate cancer researcher or clinician. Submission to this award requires a mentor, appropriate to the proposal, who has experience in prostate cancer 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 research.

2. Training Program and Environment: The PI must outline an individualized training program designed to prepare him/her for an independent career in prostate cancer research or patient care.

C. Eligibility

Prostate Cancer Training Awards provide research traineeship opportunities to individuals in the early stages of their careers under the guidance of an experienced prostate cancer researcher. PIs must have a ***designated*** mentor. Other eligibility requirements for the different levels of achievement are as follows:

- **Predoctoral Ph.D. and M.D./Ph.D. PIs**
  - Must be graduate students enrolled full-time in an accredited doctoral program; and
  - Must have successfully completed comprehensive examinations or otherwise met predissertation requirements by October 1, 2009.

- **Postdoctoral Ph.D. PIs**
  - Must have successfully defended a doctoral thesis by October 1, 2009; and
  - Must have 3 years or less of postdoctoral fellowship experience by October 1, 2009.
- **Postdoctoral M.D. PIs**
  - Must hold an M.D. degree;
  - Must be able to participate at a minimum of 40% level of effort for the performance period of the traineeship; and
  - By August 1, 2009:
    - Must be enrolled in an accredited intern training program; ***or***
    - Must be enrolled in an accredited residency or fellowship training program with at least 2 years of training remaining; ***or***
    - If not enrolled in an accredited intern, residency, or fellowship training program, must be within 3 years of the last formal training.

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

D. Funding

- **Predoctoral Ph.D. and M.D./Ph.D. PIs**
  - The maximum period of performance is 3 years.
  - The maximum allowable funding for the entire period of performance is **$92,500** in direct costs.
- **Postdoctoral Ph.D. PIs**
  - The maximum period of performance is 2 years.
  - The maximum allowable funding for the entire period of performance is **$115,000** in direct costs.
- **Postdoctoral M.D. PIs**
  - The maximum period of performance is 2 years.
  - The maximum allowable funding for the entire period of performance is **$120,000** in direct costs.
  - Up to **$60,000 per year** can be requested in direct costs.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct costs in each category of PIs listed above. In addition to the direct costs, indirect costs will not exceed 8% of the direct costs for these proposals. 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
- Stipends
- Tuition
- Seminars, courses, and textbooks
- Publication costs
- Travel to scientific/technical meetings for the PI only
- Travel between collaborating institutions

Funds may not be used for supplies, equipment, or research with animals, human subjects, or human biological substances.

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 $4.7M of the $80M FY09 PCRP appropriation to fund approximately 41 Prostate Cancer Training Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

E. Award Administration

A change in PI or mentor is not allowed for the Prostate Cancer 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 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**
Confidential Letters of Recommendation:	**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/).

The PI and Organization identified in the application submitted through Grants.gov should be the same as those identified in the pre-application; however, if there is a change in PI or Organization after submission of the pre-application, the PI must contact the CDMRP 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

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 pre-application deadline***. In addition to award-specific information, 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 Narrative (LOI)
- List of Individuals Providing Confidential Letters of Recommendation

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 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 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 (8-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 and how the proposed training will promote the PI's career in the area of prostate cancer research or patient care. Discuss the PI's career plans after the completion of this award.

     Training Program: Describe the training plan, which may include conferences, seminars, teaching responsibilities, and/or clinical responsibilities. Provide a timeline. Include a description of coursework, laboratory techniques, and journal clubs. Describe the mentor's background and experience in prostate cancer research and explain how the mentor will assist the PI in developing his or her career. Explain how the training program is supported by the 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 using the general outline provided below:

     - **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 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. ***Funds may not be used for supplies, equipment, or research with animals, human subjects, or human biological substance.***

- 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)
  - Transcripts
  - List of Dissertation Committee Members (if applicable)
  - Letters of Institutional Support
  - 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 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)

- PI Biographical Sketch
- PI Current/Pending Support
- Key Personnel Biographical Sketches

  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 Letters of Recommendation (two-page limit per letter recommended): In addition to the completed Grants.gov application package of forms and attachments, Prostate Cancer Training Award 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 training, career development, and mentorship in prostate cancer research. The mentor should address the following in his or her letter of recommendation:
  - 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 training 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 predoctoral students, 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 Current/Pending Support section); and
  - The degree to which the PI participated in idea development and proposal preparation, and the degree to which the PI will participate in the execution of the proposal if funded.

- ***Two additional confidential letters of recommendation*.**

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

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.htm.

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 correcting 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., Impact Statement or Statement of Eligibility).

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**
  - How the PI's achievements (as reflected by academic performance, awards, honors, and previous funding) indicate his or her potential for successful training in prostate cancer research.
  - How the PI's stated career goals demonstrate a commitment to pursuing a career as a prostate cancer researcher or clinician.

- How the letters of recommendation from the mentor and others support the PI's potential for a productive career in prostate cancer research
- To what degree the proposed levels of effort are appropriate for successful conduct of the proposed work.
- Whether the PI meets the appropriate eligibility requirements.

- **Mentor**
  - How the mentor's research experience, research program, committed resources, and level of effort are appropriate for the proposed training program.
  - 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.
  - Whether the quality of the proposal suggests that the mentor provided appropriate guidance in its preparation.

- **Training Program and Environment**
  - How the training program addresses issue(s) related to prostate cancer research or patient care.
  - How the individualized training program augments the PI's expertise.
  - How well the training will prepare the PI for an independent career in prostate cancer research or patient care.
  - How the scientific environment is appropriate for the proposed training.
  - How the training requirements are adequately supported by the availability of facilities and resources (including collaborative arrangements).
  - How the quality and extent of institutional support are appropriate (M.D. PIs only).

- **Impact**
  - How the project, if successful, could make an original and significant contribution to the goals of conquering prostate cancer and advancing research on the prevention, detection, diagnosis, or treatment of the disease.
- **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 the research project is appropriate for the training program and the level of training for the PI.
  - How well the research project addresses an issue related to prostate cancer research or patient care.

- Whether the research project 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 Areas**
  - How well the proposed research project responds to one or more 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: Criteria used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio include:

- 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 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 maximum allowed by 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

1. Program Announcement/Funding Opportunity, application 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/) portal should be directed to 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 Principal Investigators (PIs) of changes made to this Program Announcement 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.