# **Program Announcement**

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

**Prostate Cancer Research Program (PCRP)** 

# **Physician Research Training Award**

Funding Opportunity Number: W81XWH-08-PCRP-PRTA

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#### I. HELPFUL INFORMATION

#### A. Contacts

1. Program announcement, proposal format, or required documentation: To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079

Fax: 301-619-7792

Email: cdmrp.pa@amedd.army.mil

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

Phone: 301-682-5507

Website: https://cdmrp.org

Email: <a href="mailto:help@cdmrp.org">help@cdmrp.org</a>

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

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

Email: <a href="mailto:support@grants.gov">support@grants.gov</a>

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

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

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

# C. Commonly Made Mistakes

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

# II. FUNDING OPPORTUNITY DESCRIPTION

# A. Program History and Objectives

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

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

• Support innovative research by individual investigators in multiple disciplines;

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

# **B.** Award Description

The PCRP Physician Research Training Award was introduced in FY03. Since then, 82 proposals have been received and 32 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, equipment, and travel to scientific/technical meetings. 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 proposals from all areas of basic, preclinical, behavioral, and epidemiological research.

# C. Eligibility

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

# D. Funding

Funding for a Physician Research Training Award can be requested for up to \$130,000 per year for direct costs for a minimum performance period of 3 years and a maximum performance period of 5 years, plus indirect costs as appropriate. Indirect costs will not exceed 8% of the direct costs for these proposals.

Within the guidelines provided in the Application Instructions, 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, equipment, and travel to scientific/technical meetings
- Travel between collaborating institutions

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 the next PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting (tentatively scheduled for 2010).

The CDMRP expects to allot approximately \$4.7M of the \$80M FY08 PCRP appropriation to fund approximately eight Physician Research Training 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 upon 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.

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

• Confidential Letter of Support Deadline: 5:00 p.m. Eastern time, June 12, 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 <u>CDMRP eReceipt system</u> (<a href="https://cdmrp.org/">https://cdmrp.org/</a>) and (2) a proposal submission through <u>Grants.gov</u> (<a href="https://www.grants.gov/">https://www.grants.gov/</a>).

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

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

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

- 1. Proposal Information
- 2. Proposal Contacts
- 3. Collaborators and Conflicts of Interest
- 4. Letter of Intent Narrative
- 5. Contact Information for Confidential Letter of Support

# 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 (<a href="www.grants.gov">www.grants.gov</a>). No paper copies will be accepted.

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

The package includes:

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

#### 2. Attachments Form

Attachment 1: Project Narrative (8-page limit)
Describe the proposed project in detail using the outline below. *Preliminary data* are not required but may be included.

**PI's Career Goals:** Describe the PI's career goals 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. 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 proposal 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
  - o 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.

- o Letters of Collaboration (if applicable)
- Attachment 3: Technical and Public Abstracts

Both the training program and the research project should be emphasized.

- Attachment 4: Statement of Work
- Attachment 5: Impact Statement

State explicitly how the proposed work will have an impact on fostering the PI's expertise and future career in prostate cancer research and clinical medicine.

- Attachment 6: Statement of Eligibility
- Attachment 7: 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

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 Budget Form

Budget Justification

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

# **6.** R&R Subaward Budget Attachment(s) Form (if applicable)

Confidential Letter of Support (two-page limit): In addition to the completed Grants.gov application package of forms and attachments, Physician Research Training Award proposals 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 proposal preparation, and the degree to which the PI will participate in the execution of the proposal if funded.

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

#### V. INFORMATION FOR PROPOSAL REVIEW

# A. Proposal Review and Selection Overview

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

The peer review and program review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that proposal and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

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

#### B. Review Criteria

**1. Peer Review:** All proposals 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 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.
- o 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.
- o Whether the PI meets the appropriate eligibility requirements.

# 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.
- o 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 proposal 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 or clinical medicine.
- How well the PI has outlined an individualized training program that augments his or her expertise.
- o 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.
- o How the quality and extent of other institutional support are appropriate.

## Impact

o How the training program will have an impact on the PI's expertise and future career in prostate cancer research and clinical medicine.

# Research Strategy and Feasibility

- How the research project for the training program and the level of training for the PI are appropriate to further his or her career in prostate cancer research and clinical medicine.
- o How well the research project addresses an issue related to prostate cancer or clinical medicine.
- o 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.

# Budget

- o How the budget is appropriate for the proposed research.
- **2. Programmatic Review:** Criteria used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio include:
  - Ratings and evaluations of the peer reviewers,
  - Programmatic relevance,
  - Relative impact,

- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

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

#### VI. COMPLIANCE GUIDELINES

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

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

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

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

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

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