Program Announcement

I. GENERAL INFORMATION

This program announcement is being released before the receipt of Federal funds appropriated in a bill for this program; funding of proposals received in response to this program announcement is contingent on the receipt of these funds at the United States Army Medical Research and Materiel Command (USAMRMC).

- A. Title of Award: Prostate Cancer Research Program (PCRP) Prostate Cancer Training Award.
- **B. Program Name:** Department of Defense (DOD) Fiscal Year 2006 (FY06) PCRP.
- C. Funding Opportunity Number: W81XWH-06-PCRP-PCT.
- **D. Agency Name:** USAMRMC, Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.
- E. Agency Contact(s)
 - 1. Questions related to the program announcement, proposal format, or required documentation: Applicants should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079 Fax: 301-619-7792

E-mail: cdmrp.pa@amedd.army.mil

Mail: Commander

US Army Medical Research and Materiel Command

ATTN: MCMR-ZB-C (PC06-PCT) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: A help line for questions relating to proposal submission and the CDMRP eReceipt Online Proposal Submission System is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. Help also is available on the CDMRP website or by e-mail as follows:

Website: https://cdmrp.org (User's Guide located in upper right corner of the

proposal submission website)

E-mail: help@cdmrp.org

F. Anticipated Instrument Type(s): The USAMRMC executes its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request from:

Fax: 301-619-2937

E-mail: qa.baa@amedd.army.mil

Mail: Director

US Army Medical Research Acquisition Activity

ATTN: MCMR-AAA-R 820 Chandler Street

Fort Detrick, MD 21702-5014

- **G.** Catalog of Federal Domestic Assistance (CFDA) Number 12.420: Military Medical Research and Development.
- **H. Website to Access Application Package:** Proposals must be submitted at https://cdmrp.org. This website contains all the information, forms, documents, and links needed to apply. Applicants experiencing difficulty downloading documents should contact the CDMRP as indicated in Subsection I.E.2.
- **I. Award/Regulatory Approval:** The applicant may not use funds from this award to directly support research involving human subjects, human biological substances, or laboratory animals.

II. FUNDING OPPORTUNITY DESCRIPTION

- **A. Program History:** The Prostate Cancer Training Award is one of the mechanisms of the DOD PCRP, which was established in FY97 to promote innovative research directed toward eliminating prostate cancer. Appropriations for the PCRP from FY97 through FY05 totaled \$650 million (M). The Prostate Cancer Training Award is a new mechanism for FY06 that consolidates previous PCRP training mechanisms. *The new award mechanism includes Predoctoral, Postdoctoral, Medical Student, Resident, and Fellow Traineeships.* In FY05, the PCRP received 130 Postdoctoral, 73 Predoctoral and 19 Resident and Medical Student proposals. Of these, 42 Postdoctoral, 30 Predoctoral and 2 Resident and Medical Student proposals were funded. The FY06 PCRP appropriation is \$80M.
- **B. Program Objectives:** The overall goal of the FY06 PCRP is to find and fund innovative, high impact research that seeks to (1) prevent prostate cancer, (2) detect prostate cancer, (3) cure prostate cancer, and (4) improve the quality of life for individuals living with prostate cancer and for their families.

III. AWARD INFORMATION

The Prostate Cancer Training Award provides training opportunities focused on prostate cancer research or patient care to individuals in the early stages of their careers. These awards provide

primarily salary support for the trainee and require the active involvement of a mentor who is an established prostate cancer researcher from an appropriate discipline (clinical research, pathology, urology, etc.). The mentor must have a demonstrated record of funding and publications in prostate cancer research. The focus of these awards is on the applicant, the mentor, and the training environment. All Prostate Cancer Training Award proposals are to be written with appropriate direction from the mentor and signed by the trainee as the Principal Investigator (PI) and author of the proposal. Applicants may apply for Predoctoral, Postdoctoral, and Medical Student Traineeships through this award mechanism (see Section IV.A for eligibility requirements).

Funding for the Prostate Cancer Training Award can be requested as follows:

Category	Maximum Funding (direct costs)	Maximum Duration
Predoctoral M.D. Applicants	\$32,500	1 year
Predoctoral Ph.D. and M.D./Ph.D. Applicants	\$92,500	3 years
Postdoctoral Ph.D. Applicants	\$115,000	2 years
Postdoctoral M.D. Applicants	\$60,000- \$120,000	1-2 years

Projects requiring lower levels of funding also may be submitted. These funds can cover salary, stipends, tuition, seminars and courses, and travel to scientific/technical meetings. In addition, funding of \$1,800 must be requested for travel to a PCRP Awardees Meeting (tentatively scheduled for the fall of 2007). Although animal and human research may be proposed, such research will not be funded by these awards. These funds may not be used for supplies or equipment. Any funding (direct costs) in excess of the allowable stipend must be used as direct support for the trainee. In addition to direct costs, a maximum of 8% of direct costs is allowed for indirect costs.

The nature of the PCRP does not allow for renewal of grants or supplementation of existing grants.

The CDMRP expects to allot approximately \$11M of the \$80M FY06 PCRP appropriation to fund approximately 75 Prostate Cancer Training Awards depending on the quality and number of proposals received.

IV. ELIGIBILITY INFORMATION

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

• Predoctoral M.D. Applicants

o Must be enrolled in an accredited medical school; and

 Must be able to participate at a 40%-100% level of effort for the 1-year performance period of the traineeship.

• Predoctoral Ph.D. and M.D./Ph.D. Applicants

- Must be graduate students enrolled full time in an accredited doctoral program at the time of proposal submission; and
- Must have successfully completed comprehensive examinations or otherwise met predissertation requirements at the time of proposal submission.

• Postdoctoral Ph.D. Applicants

- Must have completed all academic requirements for a doctoral degree at the time of award negotiation;
- Must have successfully completed a doctoral thesis at the time of award negotiation;
 and
- Must have 3 years or less of postdoctoral experience at the time of proposal submission.

Postdoctoral M.D. Applicants

- Must hold an M.D. degree;
- Must be able to participate at a 40%-100% level of effort for the performance period of the traineeship; and
- o At the time of proposal submission:
 - Must be enrolled in an accredited intern training program; or
 - Must be enrolled in an accredited residency or fellowship training program with at least two years remaining; *or*
 - If not enrolled in an accredited intern, residency, or fellowship training program, must be within three years of receiving an M.D. degree.

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined in <u>Subsection IV.B</u>, "Institutions" below.

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business only with responsible recipients. The USAMRMC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov. (Reference Department of Defense Grant and Agreement Regulations (DODGAR) 25.110.)

B. Institutions: Eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

A DOD goal is to allocate funds for the CDMRP peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders. Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at http://cdmrp.army.mil/spp under "Minority Institutions."

Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

C. Duplicate Submissions: Submission of the same research project to different FY06 PCRP award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

- **A. Proposal Components Summary:** This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement. Proposals will be evaluated according to peer and programmatic review criteria in Section VI.
 - **1. Applicant Responsibility:** The applicant is responsible for entering and/or uploading the following information into the CDMRP eReceipt Online Proposal Submission System at https://cdmrp.org:

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	Typed	Copy the LOI into the data field. Click the "Save and Forward Letter of Intent" button to automatically create the LOI.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.

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¹Executive Orders 12876, 12900, and 13021

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	Typed	Copy the LOI into the data field. Click the "Save and Forward Letter of Intent" button to automatically create the LOI.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.
Proposal Contacts	Proposal Contacts	Typed	Enter contact information for the applicant and the Contract Representative at the applicant's institution.
Collaborators and Conflicts of Interest (COI)	Collaborator/ COI	Typed	Enter information about collaborators and others outside the scope of the proposal who may have a COI in the review of this proposal.
Proposal Abstracts, Impact Statement, and Statement of Work (SOW)	Abstract/ Impact/SOW	Typed or Cut and Paste	Enter the Technical Abstract, Public Abstract, Impact Statement, and SOW in separate data fields.
Proposal Main Body	Required Files	PDF	Upload as a PDF file.
Supporting Documentation	Required Files	PDF	Upload as a PDF file.
Budget Information	Required Files	PDF	Upload as a PDF file.
Regulatory Documents	Required Files	PDF	Upload the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance forms.

2. Contract Representative Responsibility: The Contract Representative (CR) or institutional official responsible for sponsored program administration (or equivalent) at the applicant's institution is responsible for the following:

Item	Tab	Format	Action
Contract Representative's Contact Information Profile	My Profile for the CR	Typed	Complete before electronic approval of all submission components.
USAMRAA ^a - Required Documents	My Profile for the CR	PDF	Upload the Rate Agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements.

Item	Tab	Format	Action
Approval	CR Approval	Click Approval Button	Click the button to approve the Proposal Information, Proposal Contacts, Collaborators and COI, Abstracts/Impact Statement/SOW, and Required Files <i>before</i> the submission deadline of 5:00 p.m. Eastern time, April 18, 2006.

^aUS Army Medical Research Acquisition Activity

B. Proposal Format: Proposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt Online Proposal Submission System at https://cdmrp.org. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire and learn to use the appropriate software well in advance of the submission deadline. The instructions in this subsection must be followed carefully to prepare proposals for PDF submission.

The main body of the proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on the computer screen and submitted via the CDMRP eReceipt Online Proposal Submission System.

- **Font Size:** 12 point or larger.
- Font Type: Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (approximately 19.05 cm x 25.40 cm).
- Color, High-Resolution, and Multimedia Objects: Proposals may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 MB. Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Internet URLs:** URLs directing reviewers to websites containing significant additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are allowed.
- Language: English.

Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.

C. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Failure to adhere to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection.

The following will result in administrative rejection of the entire proposal before it reaches peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.

For any sections of a proposal with a defined page limit, pages exceeding the specified limit will be removed from the proposal 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.

The electronic PDF file uploaded in the CDMRP eReceipt Online Proposal Submission System is the official proposal submission file. After conversion of word processing documents to PDF files and before electronic submission, applicants should review their files to ensure that the proposal complies with the preparation guidelines outlined in this program announcement.

- **D.** Letter of Intent (LOI): An LOI (a brief description of the proposal) is entered in a data field under "My Proposals: Create New Proposal". The LOI is saved when the "Save and Forward Letter of Intent" button is selected. The LOI may be modified under "Proposal Information" at anytime before the applicant submits this information by clicking "Finalize for CR Approval." The LOI should be submitted by *March 21, 2006* at https://cdmrp.org.
- **E. Proposal Information:** Applicants are required to submit the Proposal Information as described in https://cdmrp.org before uploading the proposal, supporting documentation, and budget information.
 - A *Title/Referral Page* for the proposal will be generated from the information uploaded in eReceipt and appended to the proposal electronically by the CDMRP eReceipt system.
- **F. Proposal Contacts:** The Proposal Contacts *must* include the e-mail address of a Contract Representative authorized to negotiate on behalf of the applicant's institution. The Proposal Contacts must be approved by the Contract Representative at the applicant's institution.

- **G.** Collaborators and Conflicts of Interest (COI): To avoid COI during the review process, list the names of all scientific participants in the proposal including collaborators, consultants, and subawardees. In addition, list the names of individuals outside the scope of this proposal who may have a COI in reviewing this proposal.
- **H. Proposal Abstracts 5,700-character limit including spaces (approximately one page), for each abstract:** Each abstract must include the applicant's name and the title of the proposal. A structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important in both the peer review and programmatic review processes. Programmatic review is based on the Integration Panel's review of these two abstracts as part of the peer review summary statements; therefore, it is of paramount importance that the applicant submits abstracts that describe the proposed work fully. Each abstract must be entered into the appropriate data field under the "Abstract/Impact/SOW" tab of the CDMRP eReceipt system.

Applicants can type the abstracts or "cut and paste" them from a word processing application into the respective data fields. *Spell out all Greek letters, other non-English letters, and symbols.*

Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Proprietary or confidential information should *not* be included in either the technical or the public abstract.

- **1. Technical Abstract:** Sample technical abstracts can be found at https://cdmrp.org/samples.cfm. The structured technical abstract must provide a clear and concise overview of the proposed work. Use the outline below when preparing the structured technical abstract.
 - Background: Present the ideas and reasoning behind the proposed work.
 - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design including appropriate controls.
 - Impact: Provide a brief statement explaining the impact of the proposed work to the program goals. Describe how the proposed project will have an impact on prostate cancer research or patient care.
- 2. Public Abstract: Sample public abstracts can be found at https://cdmrp.org/samples.cfm. The public abstract is intended to communicate the purpose and rationale of the study to a non-scientifically trained audience. The public abstract is an important component of the proposal review process because consumer advocates, who are part of the review and funding decision process, use this abstract as a part of their review. Do not duplicate the technical abstract.
 - Describe the applicant's career goals in prostate cancer research or patient care.

- How does the training program support the applicant in attaining these goals?
- How does the research plan support the applicant in attaining these goals?
- Describe the ultimate applicability of the research.
 - What types of patients will it help and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a consumer-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
 - What types of contributions will this study make to advance research?
 - o How will the research enhance this or other studies being conducted?

I. Impact Statement – 5,700-character limit including spaces (approximately one page): The Impact Statement is captured as a data field under the "Abstract/Impact/SOW" tab in the CDMRP eReceipt system. Applicants can type the Impact Statement into the data field or "cut and paste" it from a word processing application.

State explicitly how the proposed work will have an impact on prostate cancer research or patient care. Describe how the expected results of the proposal will contribute to the goals of conquering prostate cancer and advancing research in the field. Clearly and simply state how the research will significantly advance methods, concepts, prevention, diagnosis, or treatment of prostate cancer or quality of life for patients. The Impact Statement, which will be available at both peer and programmatic reviews, is often cited by consumer advocates during the review and funding decision processes.

J. Statement of Work – 11,400-character limit including spaces (approximately two pages): The SOW is captured as a data field under the "Abstract/Impact/SOW" tab in the CDMRP eReceipt system. Applicants can type the SOW into the data field or "cut and paste" it from a word processing application.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's SOW must include DOD-funded tasks only. Sample SOWs can be found at https://cdmrp.org/samples.cfm.

The SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Identify the timeline and milestones for the work over the performance period for the proposed effort;
- For animal and human studies (including tissue, anatomical, or biological substances), indicate the sample size projected or required for each task;
- Identify methods; and

• Identify outcomes, products, and deliverables for each phase of the project.

K. Proposal Main Body: Start section on a new page; 10-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the proposal.

The proposal main body is uploaded as a PDF file under the "Required Files" tab of the CDMRP eReceipt system.

Describe the proposed project using the following outline:

- 1. Applicant's Career Goals: Describe the applicant's career goals and how the proposed training will promote the applicant's career in the area of prostate cancer research or patient care. Discuss the applicant's career plans after the completion of this award.
- **2. Training Program:** Describe the training plan, which may include conferences, seminars, teaching responsibilities, or clinical responsibilities. Provide a timeline. For predoctoral and postdoctoral traineeships 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 applicant in developing his or her career. Explain how the training program is innovative and 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.
- **3. Research Project:** Describe the proposed project using the general outline provided below:
 - **Background:** Briefly state the rationale and the purpose of the proposed research. Present published data relevant to prostate cancer and the proposed project (cite relevant literature). Emphasize experience pertinent to this proposal. Preliminary data may be included, although they are not required.
 - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
 - **Specific Aims:** Concisely explain the project's specific aims.
 - **Research Strategy:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation. Include appropriate controls and contingency plans. If using either human subjects or human biological samples, include a detailed plan for the recruitment of subjects and/or the acquisition of samples.
- **L. Supporting Documentation:** Submit only material specifically requested in this program announcement. *This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.* Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal.

Supporting Documentation must be uploaded as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. All documents or letters that require signatures must be signed and incorporated into the supporting documentation file before it is submitted.

The first item in the Supporting Documentation file is the <u>Checklist/Table of Contents</u> page. The requested, allowable items in this section must be listed in the Checklist/Table of Contents; these include:

- **1. Abbreviations: Start section on a new page; one-page limit.** Provide a list of all acronyms, abbreviations, and symbols used in the main body of the proposal.
- **2. References: Start section on a new page; no page limit.** List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **3. Biographical Sketches: Four-page limit per individual.** Include biographical sketches for all key personnel including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower proposal scores. The <u>Biographical Sketch form</u> may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.
- **4. Existing/Pending Support: Start section on a new page; no page limit.** List the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the applicant and key personnel on a separate page. If no support exists, enter "None." Proposals submitted under this program announcement should not duplicate other funded research projects.
- **5. Facilities/Equipment Description: No page limit.** Describe the facilities available for performing the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment available for use at no cost to the USAMRMC. Indicate whether Government-owned facilities or equipment are proposed for use.
- **6. Transcripts:** Provide official transcripts from undergraduate institutions and graduate-level courses completed to date. All foreign-language transcripts must be accompanied by an English translation.
- 7. Letters of Recommendation: The applicant must request three letters of recommendation through "Required Files" tab of the CDMRP eReceipt system. An e-mail generated from eReceipt will notify the individuals selected to provide confidential letters of recommendation. This e-mail also will provide instructions for the selected individual to upload the letter of recommendation. The applicant will be able to monitor only whether the letters have been received; the applicant will not be able to view these letters. All letters must be submitted before the receipt deadline.

- A letter of recommendation from the mentor describing his or her commitment to the applicant's training, career development, and mentorship in prostate cancer research. The mentor should address the following in his or her letter of support:
 - o The applicant's potential to become a prostate cancer researcher;
 - o The mentor's interactions with the applicant during the applicant's training;
 - The training environment, including ongoing prostate cancer research at the institution, and how this training environment promotes innovation in its activities to train prostate cancer researchers;
 - The research training program in which the applicant 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 applicant 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 trainee's project (specific
 details on existing support should be covered in the Existing/Pending Support
 section; see <u>Subsection V.L.4</u>); and
 - The degree to which the applicant participated in idea development and proposal preparation, and the degree to which the applicant will participate in the execution of the proposal if funded.
- Two additional letters of recommendation.

8. Letters of Support: Provide the following:

- Letter of institutional support (for M.D. Applicants only): A letter of institutional support describing the institution's commitment to fostering the applicant's research career, as reflected by (1) the extent to which the applicant will be relieved of other academic and clinical 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.
- **9.** Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five publications are included in the submission, the extra items will not be peer reviewed.

- **10. Statement of Eligibility:** The <u>Statement of Eligibility Form</u> must be signed by the Department Chair, Dean, or equivalent official verifying that the applicant meets the relevant eligibility criteria (see <u>Section IV.A</u>).
- **M. Budget Information:** Applicants must complete the <u>Detailed Cost Estimate form and the Budget Justification form</u>, and upload them as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. When a proposal requesting funding as part of a larger study is submitted, the proposal's budget justification should include only DOD-funded tasks.
 - **1. Funding Restrictions:** Funding for the Prostate Cancer Training Award can be requested as follows (see Section IV.A for definitions of categories):

Category	Maximum Funding (direct costs)	Maximum Duration
Predoctoral M.D. Applicants	\$32,500	1 year
Predoctoral Ph.D. and M.D./Ph.D. Applicants	\$92,500	3 years
Postdoctoral Ph.D. Applicants	\$115,000	2 years
Postdoctoral M.D. Applicants	\$60,000- \$120,000	1-2 years

Projects requiring lower levels of funding also may be submitted. These funds can cover salary, stipends, tuition, seminars and courses, and travel to scientific/technical meetings. In addition, funding of \$1,800 must be requested for travel to a PCRP Awardees Meeting (tentatively scheduled for the fall of 2007). Although animal and human research may be proposed, such research will not be funded by these awards. These funds may not be used for supplies or equipment. Any funding (direct costs) in excess of the allowable stipend must be used as direct support for the trainee. In addition to direct costs, a maximum of 8% of direct costs is allowed for indirect costs.

2. Detailed Cost Estimate Form and Budget Justification Instructions: Budget is an important consideration in both peer review and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. Organizations must provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research. All costs must be entered in U.S. dollars.

The USAMRMC encourages in-kind contributions and cost-sharing for CDMRP-supported research. In-kind contributions may include support of services (e.g., laboratory services and salaries of personnel), real property and equipment, and/or supplies (e.g., drugs, devices, reagents) directly benefiting and specifically identifiable to the research project.

Costs proposed must conform to the following regulations and principles:

• Commercial Firms: Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31 (http://farsite.hill.af.mil), Contract Cost Principles and Procedures.

- Educational Institutions: Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- Nonprofit Organizations: OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations
 (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- State, Local, and Tribal Governments: OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments (http://www.whitehouse.gov/omb/grants/grants_circulars.html).

Follow the instructions below when providing the information requested in the Detailed Cost Estimate form.

a. Personnel

- i. Name: Beginning with the applicant, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. *The applicant must be identified as the Principal Investigator of the proposal.*
- **ii. Role on Project:** Identify the role of each participant listed. Describe his or her specific functions in the Budget Justification section of the Detailed Cost Estimate form.
- **iii. Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50%, note this with an asterisk (*) and provide a full explanation in the Budget Justification section of the Detailed Cost Estimate form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- iv. Annual Base Salary: Enter the annual institutional base salary for the trainee.
- v. Percentage of Effort on Project: The applicant's qualifications and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. List the percentage of each appointment to be spent on this project for each key staff member. Include the percent effort of all unpaid professional personnel, including the mentor.
- vi. Salaries Requested: Enter the salaries in whole dollar figures for the trainee. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.

- **vii.** Fringe Benefits: Fringe benefits may be requested for the trainee in accordance with institutional guidelines, provided the costs are treated consistently for all sponsors by the applicant's organization. Documentation to support the fringe benefits should be provided.
- **viii.** Totals: Calculate the totals for the trainee and enter these as subtotals in the columns indicated.
- **b.** Consultant Costs: Provide the names and organizational affiliations of all consultants. However, funds cannot be used for consultant costs.
- c. Major Equipment: It is the policy of the DOD that all commercial and nonprofit recipients provide the equipment needed to support proposed research. *The purchase of major equipment from these funds is not allowed.*
- **d. Materials, Supplies, and Consumables:** Funding for this award cannot be used for the purchase of materials, supplies, or consumables.
- **e. Travel Costs:** Costs for travel to scientific/technical meetings may not exceed \$1,800 per year. Additional travel funds of \$1,800 must be requested to attend a PCRP Awardees Meeting (tentatively scheduled for the fall of 2007).

Travel costs associated with the execution of the proposed work should be entered in this section. If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly \$1,800 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the U.S. requires prior approval from the US Army Medical Research Acquisition Activity (USAMRAA).

- f. Research-Related Subject Costs: Not applicable to the Prostate Cancer Training Award Proposals.
- **g.** Other Direct Costs: Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.
- h. Subaward Costs: Not applicable to the Prostate Cancer Training Award
- i. Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed with a statement identifying whether the proposed rates are provisional or fixed. A maximum indirect cost rate of 8% of the direct costs is allowed.

- j. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals in each budget category for all additional years of support requested and itemize these totals in the Budget Justification section of the Detailed Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Directs costs, indirect costs, and the total cost for the entire proposed period of support should equal the amount entered in the "Required Files" tab at https://cdmrp.org.
- **3.** Budget Justification (third page of the Detailed Cost Estimate form): Each item in the budget must be clearly justified in the Budget Justification section of the Detailed Cost Estimate form.
- **4. Federal Agency Financial Requirement:** Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

Start the plan on a new page at the end of the Budget Information section. The Federal Agency Financial Plan must be uploaded as part of the budget information before the submission deadline of 5:00 p.m. Eastern time, April 18, 2006.

- **N. Regulatory Requirements:** Completed and signed copies of the <u>Certificate of Environmental Compliance</u> and <u>Principal Investigator Safety Program Assurance</u> form must be uploaded under the "Required Files" tab of the CDMRP eReceipt system as separate PDF files.
- **O. USAMRAA-Required Documents:** The Contract Representative at the applicant's institution must upload the current version of the institution's negotiated Rate Agreement, the Certifications and Assurances for Assistance Agreements, and the Representations for Assistance Agreements. These documents must be uploaded as separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system by the proposal submission deadline.
- **P. Submission Date and Time:** Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution by the deadline. Proposals that are incomplete or not approved electronically before the deadline will not be considered for review. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, April 18, 2006 deadline.

The timeline for the Prostate Cancer Training Awards is:

Online Letter of Intent: Expected by *March 21, 2006*

Online Proposal Information: Required prior to proposal submission

Proposal Submission/Approval Deadline: S:00 p.m. Eastern time, April 18, 2006

Peer Review (First Tier): July 2006

Programmatic Review (Second Tier): September 2006

Request for Additional Documents: As early as 2 weeks after the completion of

programmatic review

Notification Letter: Approximately 4 weeks after the completion

of programmatic review

Award Start Date: Anticipated between December 2006 and

September 2007

Q. Electronic Submission Requirements: Electronic submission is required. Only proposals submitted as PDF files through the CDMRP eReceipt system at https://cdmrp.org will be accepted.

Several steps are critical to successful proposal submission:

- The Proposal Information must be "Finalized for CR Approval" before the proposal is submitted. Applicants are encouraged to begin this part of the submission process early.
- Proposal Contacts must be "Finalized for CR Approval" before the proposal is submitted. The e-mail address of a Contract Representative at the applicant's institution must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate with their Contract Representative early in the application process.
- The Contract Representative authorized to negotiate on behalf of the applicant's institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will *not* accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, April 18, 2006 deadline.
- Some items in the proposal including figures, tables, graphs, letters, or publications will
 need to be scanned electronically. These documents should be scanned at a resolution of
 300 dpi or less.
- Applicants are encouraged to retain a date and time-stamped copy of the proposal component files as prepared by word processing software (e.g., Microsoft Word, WordPerfect) as well as the original PDF conversion file.
- The Detailed Cost Estimate form and the Budget Justification form must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed and signed Certificate of Environmental Compliance and a completed and signed Principal Investigator Safety Program Assurance form. These forms must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

- 1. **Process:** The CDMRP uses a two-tier review process for proposal evaluation. The two tiers differ fundamentally. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program.
- **2. Peer Review:** Peer review is conducted by scientific and consumer reviewers. The primary responsibility of the peer reviewers is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals based on the review criteria published for each award mechanism.

Scientific reviewers are selected for their subject matter expertise and experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the peer review process by bringing the patient perspective to the assessment of science and the relevance of the research.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the peer review scores and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement.

3. Programmatic Review: Programmatic review is conducted by the Integration Panel, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the Integration Panel represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. A function of programmatic review is to structure a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. Integration Panel members base programmatic review primarily on the peer review summary statements and the proposal abstracts. The Integration Panel also may review SOWs and impact statements. Full proposals are not forwarded to programmatic review.

HBCU/MI proposals are reviewed concurrently with others in the same research area during scientific peer review. However, they may be evaluated separately during programmatic review. Consistent with the CDMRP's goal, recommendations for funding HBCU/MI proposals are based on scientific excellence and program relevance.

B. Review Criteria

1. Peer Review: Prostate Cancer Training Award proposals will be evaluated by peer reviewers according to the following criteria. The reviewers will evaluate:

• Applicant

- How the applicant'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 applicant's stated career goals demonstrate a commitment to pursuing a career as a prostate cancer researcher or clinician.
- How the mentor's letter of recommendation supports the applicant's potential for productive prostate cancer research.
- The appropriateness of the proposed levels of effort for successful conduct of the proposed work.
- Whether the applicant meets the appropriate eligibility requirements (see <u>Section</u> IV.A).

Mentor

- How the mentor is appropriately trained and well suited to guide this research project.
- o 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 applicant in prostate cancer research.
- How the mentor's research experience, research program, committed resources, and level of effort is appropriate for the proposed training program.
- o If the quality of the proposal suggests that the mentor provided appropriate guidance.

• Training Program

- How the training program addresses an issue(s) related to prostate cancer research or patient care.
- How the individualized training program augments the applicant's expertise.
- How well the training will prepare the applicant for an independent career in prostate cancer research or patient care.
- o 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).
- The quality and extent of institutional support (M.D. Applicants only).

Impact

- The impact of the training program on the applicant's expertise in prostate cancer research or patient care.
- How the project will train the applicant to make valuable contributions to the study or treatment of prostate cancer.

 How the results of the research will advance prostate cancer research or patient care if the aims of the project are achieved.

• Research Project

- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- How the research project is appropriate for the training program and the level of training for the applicant.
- How well the applicant acknowledges potential problems and addresses alternative approaches.

Budget

- o How the budget is appropriate for the proposed work.
- **2. Programmatic Review:** Criteria used by the Integration Panel to make funding recommendations that maintain the PCRP's broad portfolio include:
 - Ratings and evaluations of the peer reviewers (scientific and consumer),
 - Programmatic relevance,
 - Relative innovation and impact,
 - Program portfolio balance, and
 - Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program are selected by the Integration Panel and recommended for funding to the Commanding General, USAMRMC.

VII. AWARD ADMINISTRATION INFORMATION

- **A. Award Notices:** Each applicant will receive notification of the award status of his or her proposal. A copy of the peer review summary statement will be posted to the CDMRP eReceipt system. Applicants can expect to receive notification approximately four weeks after programmatic review.
- **B.** Administrative Requirements: Awards are made to organizations, not individuals. An applicant must submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institution, commercial firm, or Government agency (including military laboratories) to receive support. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110 and DOD Grant and Agreement Regulations) to be eligible for an award. *Any organization requesting receipt of an award through this announcement must be registered in the Central Contractor Registration (CCR)*

database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.

Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

A change in mentor is not allowed for the Prostate Cancer Training Award.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the applicant's institution. Additional documentation and justifications related to the budget may be required as part of the negotiation process.

The award start date will be determined during the negotiation process.

D. Regulatory Review

- **1. Overview:** Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal.
- **2. Certificate of Environmental Compliance:** The <u>Certificate of Environmental Compliance</u> must be submitted with the proposal. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.
- **3. Safety Program Documents:** The <u>Principal Investigator Safety Program Assurance form</u> must be submitted with the proposal.

A Facility Safety Plan is required; it will be requested at a later date. A Facility Safety Plan from the applicant's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.detrick.army.mil/crprcqsohdfsplan.asp. If the applicant's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc.

If multiple research sites/institutions are funded in the proposal, a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

- 4. Research Involving Animal Use: Not applicable for the Prostate Cancer Training Award.
- 5. Research Involving Human Subjects/Biological Substances/Cadavers: *Not applicable for the Prostate Cancer Training Award.*
- 6. Award/Regulatory Approval: Not applicable for the Prostate Cancer Training Award.
- **E. Reporting Requirements:** The Government requires reports to be submitted for continuation of the research and funding. The specific reports due to the Government will be described in each award instrument. (Full USAMRMC reporting requirements can be found at https://mrmc-www.army.mil, under "Links and Resources.") *Failure to submit required reports by the required date may result in a delay in or termination of award funding.*

Reporting requirements include the following:

- 1. **Progress Reports:** Reporting requirements consist of an annual report (for each year of effort) that presents a detailed summary of training and scientific issues and accomplishments. Copies of all scientific publications and patent applications resulting from CDMRP funding should be included in the progress reports.
- **2. Fiscal Reports:** Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

VIII. OTHER INFORMATION

- **A. Disclosure of Proprietary Information outside the Government:** By submitting a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the proposal will be used only for evaluation purposes and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding are not subject to public release.
- **B.** Government Obligation: Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

- **C. Information Service:** Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.
- **D. Inquiry Review Panel:** Applicants may submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.
- **E. Title to Inventions and Patents:** In accordance with the Bayh-Dole Act (35 USC 200 et seq.), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.
- **F. J-1 Visa Waiver:** It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

IX. ACRONYM LIST

AVI Audio Video Interleave

CCR Central Contractor Registration

CDMRP Congressionally Directed Medical Research Programs

CFDA Catalog of Federal Domestic Assistance

CFR Code of Federal Regulations

COI Conflict of Interest
CR Contract Representative
DOD Department of Defense

DODGAR Department of Defense Grant and Agreement Regulations

EPLS Excluded Parties List System
FAR Federal Acquisition Regulations

FY Fiscal Year

HBCU/MI Historically Black Colleges and Universities/Minority Institutions

hES Human Embryonic Stem

HSRRB Human Subjects Research Review Board

IRB Institutional Review Board

JPEG Joint Photographic Experts Group

M Million MB Megabyte

MPEG Moving Picture Experts Group NIH National Institutes of Health

OMB Office of Management and Budget PCRP Prostate Cancer Research Program

PDF Portable Document Format

SOW Statement of Work

TIFF Tagged Image File Format

USAMRAA US Army Medical Research Acquisition Activity
USAMRMC US Army Medical Research and Materiel Command

USC United States Code

WAV Waveform