Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Physician Research Training Award

Funding Opportunity Number: W81XWH-13-PCRP-PRTA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), August 15, 2013
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, September 5, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, September 5, 2013
- **Peer Review:** October 2013
- **Programmatic Review:** February 2014

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Prostate Cancer Research Program (PCRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The PCRP was initiated in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY12 totaled $1.21 billion. The FY13 appropriation is $80 million (M).

The mission of the FY13 PCRP is to find and fund research that will lead to the elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. Specifically, the PCRP seeks to promote highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; multidisciplinary, synergistic research; translational studies to support the fluid transfer of knowledge between bedside and bench; research on patient survivorship and quality of life; the next generation of prostate cancer investigators through mentored research; and research on disparities in the incidence and mortality of prostate cancer.

PCRP Overarching Challenges *(revised for FY13)*

Consistent with the program's mission to eliminate death from prostate cancer and enhance the well-being of men experiencing the impact of the disease, including those from disproportionately affected populations, each PCRP funding opportunity either requires or encourages (see Section I.B., Award Information below) applications to address one of the following three PCRP overarching challenges:

- Develop better tools to detect clinically relevant disease in asymptomatic men
- Distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer
- Develop effective treatments and address mechanisms of resistance for men with high risk or metastatic prostate cancer

PCRP Focus Areas *(revised for FY13)*

All applications for FY13 PCRP funding opportunities are also expected to address at least one of the following PCRP focus areas:

- **Biomarker Development:** Validation and qualification of biomarkers for early detection of clinically relevant disease or for prognosis or prediction and assessment of response to therapies
- **Genetics:** Understanding host or tumor genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for clinically relevant prostate cancer
- **Imaging:** Development of new anatomic, functional, and molecular imaging approaches for the detection and management of clinically relevant prostate cancer

- **Mechanisms of Resistance:** Understanding primary and acquired resistance to therapy
- **Survivorship and Palliative Care:** Improving the quality of life and well-being of prostate cancer patients and their families
- **Therapy:** Identification of new targets, pathways, and therapeutic modalities
- **Tumor and Microenvironment Biology:** Understanding the intrinsic and extrinsic mechanisms contributing to tumor development and the progression of prostate cancer

B. Award Information

The PCRP Physician Research Training Award (PRTA) mechanism was first offered in FY03. Since then, 154 PRTA applications have been received, and 63 have been recommended for funding**.**

The PRTA supports a mentored training experience to prepare physicians with clinical duties and/or responsibilities for productive careers in prostate cancer research. This award emphasizes equally the quality of both the research and the training proposed. The trainee is considered the Principal Investigator (PI) of the application. ***All applications for the PRTA are to be written by the PI, with appropriate direction from the mentor(s).*** The PI must demonstrate a commitment to a career as an investigator at the forefront of prostate cancer research and clinical practice; however, the PI is not required to have previous prostate cancer research experience. Applications must include a robust description of an individualized, prostate cancer-focused training plan that will provide the PI with experience in key areas relevant to the proposed work and foster the PI's development as a prostate cancer researcher. PIs who already possess extensive experience in cancer research may not be viewed as fitting the intent of this award mechanism.

This award requires the involvement of at least one designated mentor with an established research program in prostate cancer, evidenced by publications, funding, and successful mentorship. The PI and mentor(s) should work together to design robust training and mentoring plans, which may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, clinical responsibilities, grant writing, and/or other activities appropriate to the area of study. ***Training plans that will prepare physicians for careers in basic or population science research are particularly encouraged, although inclusion of translational or clinical research is allowed.*** In addition, applicants are expected to address at least one of the PCRP focus areas and are highly encouraged to address one of the PCRP overarching challenges. If the proposed project does not address any of the overarching challenges, the application should include a description to justify how the project will nevertheless address a critical need in the field of prostate cancer research and/or patient care.

This award is intended to provide aggressive protection of at least 40% of the PI's time for prostate cancer research. In addition, salary for up to a 50% combined level of effort from up to two key support personnel may be provided by this award. Up to $15,000 in funds per year from this award may be used for research supplies and equipment. These funds may be used for research with laboratory animals and human biological substances, as well as research with human subjects, provided that the funds are not used to support clinical trials. PIs may participate in clinical trials as part of their training for this award, but funding for such clinical trials must come from sources other than this award.

All investigators applying to FY13 PCRP funding opportunities are encouraged to consider leveraging resources available through the PCRP-funded Prostate Cancer Biorepository Network (PCBN) (http://www.prostatebiorepository.org) and/or the North Carolina - Louisiana Prostate Cancer Project (PCaP) (http://www.ncla-pcap.org) if retrospectively collected human anatomical substances or correlated data are relevant to the proposed studies.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

C. Eligibility Information

- The PI must be a physician with clinical duties and/or responsibilities who, at the application submission deadline, is either:
    - In the last year of an accredited graduate medical education program, either as a resident or fellow, **or**
    - Within 3 years of having initiated an appointment as an Instructor, Assistant Professor, or equivalent.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **4** years, and the minimum is **3** years.
- The maximum allowable direct costs for the entire period of performance are **$520,000** plus indirect costs. The maximum allowable direct costs ***per year*** are **$130,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for attendance at one Department of Defense (DoD) PCRP Innovative Minds in Prostate Cancer Today (IMPaCT) meeting, which is held to disseminate the results of PCRP-sponsored research. Costs associated with travel to this meeting, up to $1,800, should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary support for the PI ***(the organization is required to provide at least 40% protection of the PI's time for research)***
- Up to 50% combined salary support for one or two key support personnel (e.g., laboratory technician, research nurse, data manager)
- Up to $15,000 per year for research supplies and equipment
- Costs/Tuition for courses, seminars, and workshops (including textbooks and/or related materials)
- Publication costs
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

Shall not be requested for:

- Mentor salary

The CDMRP expects to allot approximately $4.2M of the $80M PCRP appropriation to fund approximately 5 Physician Research 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 upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-13-PCRP-PRTA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (https://cdmrp.org/).

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the preapplication, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest – Tab 3**

  FY13 PCRP Integration Panel (IP) members should not be involved in any preapplication or application. A list of FY13 PCRP IP members can be found at http://cdmrp.army.mil/pcrp/panels/panel13. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. ***Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.***

  List of Individuals Providing Confidential Letters of Recommendation: The PI ***must*** request a confidential letter of recommendation from the mentor (and co-mentor, if applicable) named in the application by entering his/her name, position title, email address, and phone numbers into the appropriate data fields. The name of at least one additional individual must also be entered to provide a letter of recommendation; however, ***the total number of letters must not exceed three.***

  The mentor(s) and other individuals will receive an email generated from the CDMRP eReceipt System containing specific instructions on how to upload the letter(s). The PI should monitor receipt of the letter(s) via the eReceipt website (the PI will not be able to view the content of the letter[s]). The confidential letter(s) of recommendation must be submitted through the CDMRP eReceipt System by 5:00 p.m. ET on the application deadline date.

The confidential letter(s) of recommendation must be submitted by the individual named in the pre-application. If this is not possible, the PI must contact the CDMRP eReceipt Help Desk for assistance at help@cdmrp.org or 301-682-5507. Specific points to address in the letter(s) of support that are unique to the award mechanism are described under "Application Submission Content and Form" below. All letters should be provided on letterhead, signed, and uploaded as a PDF file.

- **Submit Pre-Application – Tab 5**

  This tab ***must*** be completed for the pre-application to be accepted and processed by CDMRP.

- **Other Documents Tab**

  No additional documents are required.

C. Application Submission Content and Form

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/). For the Physician Research Training Award, additional application components are also required and should be submitted as directed below.

Grants.gov application package components: For the Physician Research Training Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   - **Attachment 1: Project Narrative (eight-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

     The PI must describe the proposed training and research 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 PI, mentor(s), or member(s) of the collaborating team. ***The Project Narrative must be written by the PI while also showing evidence of appropriate direction from the mentor(s).***

     PI's Career Goals: The PI should describe his/her career goals as a researcher and clinician and how the proposed training and research experience will promote his/her career development in prostate cancer research and patient care. The PI

should discuss his/her career plans and research plans after the completion of this award.

Training Plan: Describe the individualized training plan, which may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, clinical responsibilities, grant writing, and/or other activities. Provide a timeline for the training plan and describe how it is integrated with and designed to support the proposed research. Explain how the training plan is supported by the training environment; this should include a description of ongoing prostate cancer research at the organization. Include information on training or collaborations with other investigators and/or organizations.

Mentoring Plan: Describe the mentor's background and experience in prostate cancer research and training. Explain how the mentor's (and co-mentor's, if applicable) mentoring plan will assist the PI throughout the period of performance in developing toward independence in prostate cancer research. Provide details on the amount and types of planned interaction between the mentor(s) and the PI.

Research Project: Describe the proposed research project, including the background, hypothesis/purpose and rationale, broad objectives and specific aims, and methods. Address potential problem areas and present alternative methods and approaches.

Overarching Challenges and Focus Areas: Briefly describe how the proposed research and training are relevant to at least one of the PCRP focus areas and responsive to one of the PCRP overarching challenges. If the proposed project does not address any of the overarching challenges, provide a description to justify how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
    - References Cited: List the references cited (including URLs if available) in the project narrative 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).
    - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
    - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official (e.g., Designated Institutional Official for Graduate Medical Education), indicating the level of organizational 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 secure additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) opportunities for critical professional interaction with senior colleagues with established research careers. ***The letter(s) must demonstrate a commitment to allowing at least 40% effort on the project by the PI, with a concomitant commitment to reducing the PI's clinical responsibility/workload.***
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Transcripts: Include a copy of the PI's transcripts from all medical school (and graduate, if applicable) institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts.

  If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the Full Announcement page in Grants.gov) in place of the transcript.
- Mentor Qualifications (one-page limit): Include a description of the qualifications of the mentor. Specifically address the following:
  - Experience in prostate cancer research to include publications and active funding, if applicable (either the mentor or co-mentor should possess prostate cancer research experience)
  - Record and evidence of success in mentoring clinical fellows, residents, and postdoctoral fellows
- Co-Mentor Qualifications (if applicable, one-page limit): Include a description of the qualifications of the co-mentor. Specifically address the following:
  - Experience in prostate cancer research to include publications and active funding, if applicable (either the mentor or co-mentor should possess prostate cancer research experience)

- Record and evidence of success in mentoring clinical fellows, residents, and postdoctoral fellows

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  The technical abstract should be written using the outline below. Technical abstracts are used by all reviewers. Programmatic reviewers do not typically have access to the full application and therefore rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

  - Training Plan
    - The PI should describe his/her career goals and how the proposed training supports him/her in achieving these goals.
    - The PI should describe how the proposed research project will prepare him/her to make valuable contributions to the understanding and management of prostate cancer.
    - Briefly describe the mentoring plan, including the mentor(s) and relevant experience.
  - Research Plan
    - 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: Summarize how the proposed research will have an impact on progress toward the elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf."

  The lay abstract should be written using the outline below. ***Do not duplicate the technical abstract***. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

  - Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.
  - Describe the PI's career goals in prostate cancer research and patient care.
    - How does the training plan support the PI in achieving these goals?
    - How does the research plan support the PI in achieving 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 patient-related outcome?
  - If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study to advancing the field of prostate cancer research?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

  In addition to outlining tasks for the research proposed, applicants must include tasks for both the training and mentoring plans. An example of this type of SOW is available at https://cdmrp.org/Program_Announcements_and_Forms/.

- **Attachment 6: Impact Statement (one-page limit): Upload** as "Impact.pdf."

  State explicitly how the proposed research project will have an impact on prostate cancer research and/or patient care, including its contribution to the goal of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease. Describe how the proposed research addresses one of the PCRP overarching challenges or another critical issue in prostate cancer research and/or patient care.

- **Attachment 7: Eligibility Statement (one-page limit):** Upload as "Eligibility.pdf."

  Use the Eligibility Statement template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent Designated Institutional Official to verify that the PI will meet the eligibility requirements at the application submission deadline.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information. ***Note: Some of the items in this attachment may be made available for programmatic review.***
   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
     - ***Include the mentor's (and co-mentor's, if applicable) biographical sketch.***

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
    - ***Include the mentor's (and co-mentor's, if applicable) previous/current/pending support.***

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
    - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

Additional Application Components: In addition to the completed Grants.gov application package of forms and attachments, PRTA applications also require the submission of a confidential letter of recommendation from the mentor (and co-mentor, if applicable). At least one additional individual must submit a letter of recommendation ***(the maximum total number of letters is three)***. All letters of recommendation should be provided on letterhead, signed, and uploaded by the mentor(s) or other individual(s) as PDF files to the CDMRP eReceipt System.

Confidential Letters of Recommendation (two-page limit per letter recommended):

The confidential letters should include the following:

- ***A confidential letter of recommendation from each mentor,*** describing his/her commitment to the PI's training, career development, and mentorship in prostate cancer research. Mentor letters should address the following:
    - The PI's potential to become a successful and independent prostate cancer researcher in addition to continuing practice as a physician;
    - The commitment of the mentor to the training, career development, and mentorship of the PI, including details of the proposed interactions of the mentor with the PI during the PI's training;
    - The training environment, including ongoing prostate cancer research in the mentor's laboratory and in the organization as a whole, resources available, and how this environment will promote the development of the PI as a prostate cancer researcher;
    - The individualized training plan and how it will facilitate the PI's development as a successful prostate cancer physician-scientist;
    - The degree to which the PI participated in the project development and application preparation, and the degree to which the PI will participate in the execution of the application if funded.

- ***Additional confidential letters of recommendation (one is required).*** Additional letters should describe the PI's unique qualifications and accomplishments that highlight his/her potential for success as a prostate cancer researcher and clinician. Specifically, each letter should offer the writer's perspective on:
    - The PI's qualifications, characteristics, and achievements;
    - The PI's potential for productivity and desire for establishing a successful and independent career in prostate cancer research and patient care;
    - The relevance of the proposed research project to training the PI in prostate cancer research; and
    - The suitability of the mentor(s) and training environment for providing the PI with a solid foundation to support an independent career in prostate cancer research.

D. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command, based on technical merit, the relevance to the mission of the DHP and PCRP, and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the

applicant or collaborating organizations are prohibited from contacting persons involved in the 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 organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

   - **Principal Investigator**
     - How the PI's achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) are appropriate for this training award and indicate the potential for a successful career as a prostate cancer physician-scientist.
     - To what extent the PI's stated career goals demonstrate a strong personal commitment to pursuing a career as a leader in prostate cancer research and patient care.
     - To what extent the letters of recommendation from the mentor(s) and others support the PI's potential for a highly productive career as a prostate cancer physician-scientist.
     - Whether the proposed PI level of effort is appropriate for successful training and completion of the proposed work, and meets or exceeds the required 40% commitment.
   - **Mentor(s)**
     - Whether there is at least one mentor who is an established prostate cancer researcher, as evidenced by a demonstrated record of funding and publications in prostate cancer research.
     - How the mentor's (and co-mentor's, if applicable) own training and experience in prostate cancer research, and his/her research program and committed resources, support the ability to supervise the PI's training and research project.
     - Whether the proposed mentoring plan provides evidence of sufficient involvement in guiding the PI toward a successful career as an independent prostate cancer researcher.
     - To what extent the track records of the mentor(s), regarding previous trainees' career achievements and areas of interest, indicate the potential for successful training of the PI in prostate cancer research.
     - Whether the mentor letter(s) indicate(s) a high level of commitment to training the PI.
     - Whether the quality of the application suggests that the mentor(s) provided appropriate guidance in its preparation.

- **Training Plan and Environment**
    - How well the PI has outlined a detailed, individualized training plan that will effectively develop and prepare him/her for a career as an independent prostate cancer researcher.
    - Whether the training plan and research project are appropriately integrated.
    - To what extent the scientific environment is appropriate for the proposed training activities, including professional interaction with established prostate cancer researchers.
    - Whether there is a clear organizational commitment to protect at least 40% of the PI's workload for research.
    - To what extent the training and research requirements are adequately supported by the availability and accessibility of facilities and resources (including collaborative arrangements).
- **Research Project**
    - How well 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 (if included), and/or logical reasoning.
    - 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.
- **Impact**
    - To what degree the expected results of the project will contribute to the goal of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.
    - To what degree the proposed training and research project will bring the PI to the forefront of prostate cancer research and patient care.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Responsiveness to Overarching Challenges**
    - How well the proposed research addresses one of the PCRP overarching challenges or is otherwise justified as significantly addressing another critical issue in prostate cancer research and/or patient care.
- **Budget**
    - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

   a. **Ratings and evaluations of the peer reviewers**

   b. **Relevance to the mission of the DHP and FY13 PCRP, as evidenced by the following:**

      - Adherence to the intent of the award mechanism
      - Programmatic relevance in relation to the PCRP overarching challenges and focus areas
      - Relative impact
      - Program portfolio composition

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. 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:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- A FY13 PCRP Integration Panel (IP) member is named as being involved in the research proposed or is found to have assisted 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 FY13 PCRP IP members can be found at http://cdmrp.army.mil/pcrp/panels/panel13.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The PI does not meet the eligibility criteria as described in this Program Announcement/ Funding Opportunity.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

C. Reporting

Annual progress reports should include a comprehensive description of progress toward the tasks related to the training and mentoring plans as well as the research underway.

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

D. Award Transfers

Changes in PI are strongly discouraged for the PRTA. Extenuating circumstances necessitating a change of PI or mentor will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Eligibility Statement (Eligibility.pdf) as Attachment 7.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	
Additional Application Components	**Action**	**Completed**
Confidential Letters of Recommendation	Confirm upload to CDMRP eReceipt System.	