Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Laboratory - Clinical Transition Award

Funding Opportunity Number: W81XWH-12-PCRP-LCTA

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), May 3, 2012
- **Invitation to Submit an Application:** June 15, 2012
- **Application Submission Deadline:** 11:59 p.m. ET, August 23, 2012
- **Peer Review:** October 2012
- **Programmatic Review:** December 2012

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Prostate Cancer Research Program (PCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The PCRP was established in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY11 totaled $1.13 billion (B). The FY12 appropriation is $80M.

The overall goal of the FY12 PCRP is to find and fund research that will lead to the elimination of death and suffering from prostate cancer. 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

Consistent with the program's overall goal, each PCRP funding opportunity either requires or encourages (see Award Information below) applications to address one of the following PCRP overarching challenges:

- Develop effective treatments for advanced prostate cancer (i.e. disease progression with no available curative therapy)
- Distinguish aggressive from indolent disease

PCRP Focus Areas *(revised for FY12)*

All applications for FY12 PCRP funding opportunities must also address at least one of the following PCRP focus areas:

Biomarker Development: Qualification or validation of biomarkers for detection of aggressive disease, prediction and assessment of response to therapies, and prognosis and progression. These include validation studies of circulating tumor cells. Biomarker studies may include discovery if accompanied by qualification or validation.

Genetics: Understanding host or tumor genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for aggressive prostate cancer.

Imaging: Development of new anatomic, functional, and molecular imaging approaches for the detection and management of aggressive 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 Biology and Microenvironment Biology: Understanding prognosis and progression of prostate cancer.

B. Award Information (*Revised for FY12*)

The PCRP Laboratory - Clinical Transition Award (LCTA) mechanism was introduced in FY07. Since then, 72 applications have been received, and 10 have been recommended for funding.

The LCTA supports product-driven preclinical studies of promising lead agents or medical devices that have the potential to revolutionize prostate cancer clinical care. This award is intended to fund Principal Investigators (PIs) who lack support to conduct the preclinical studies needed to advance lead agents or medical devices to human testing, as follows:

Lead Agents: It is anticipated that lead agent development projects supported by this award will be generating pharmacology and toxicology data in preclinical studies for inclusion in a U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) application and/or current Good Manufacturing Practice (cGMP) production. Applicants are expected to have a validated target and to have identified either one lead agent (or a limited number of lead agents for optimization) before applying for this award. In addition, the PI should present data establishing the mechanism of action of the lead agent on the target or preliminary data demonstrating reliability, reproducibility, and effectiveness (including sensitivity and specificity). ***Lead agents are defined as novel biological and molecular or chemical therapeutic or imaging agents having potential clinical application to prostate cancer.*** Examples of lead agents include, but are not limited to, novel chemotherapeutics, antibodies, nanoparticles, imaging contrast agents, and others.

Medical Devices: Projects to be supported by this award will test medical devices in preclinical studies with the intent for FDA Investigational Device Exemption (IDE) application and/or cGMP production of the medical device. As appropriate, the PI should present preliminary data demonstrating reliability, reproducibility, and effectiveness (including sensitivity and specificity) for the medical device. Examples of medical devices include, but are not limited to, diagnostic or prognostic tests (e.g., microfluidic device, genomic and genetic microarray devices), imaging devices, and other medical technology.

Lead agents or medical devices supported by this award are expected to have high potential for commercial licensing for continued development and clinical use. The PI must provide a transition plan (including potential funding and resources) to describe how the product will progress to clinical trials and/or delivery to market after the completion of the PCRP award. ***The PCRP encourages investigators to leverage existing resources with commercial partners to increase potential gains in translating preclinical research outcomes for continued development and clinical application.***

Applications must include strong scientific rationale and preliminary data relevant to the lead agent or medical device under development. Preliminary data must document target availability and distribution in relevant human tissues and must provide substantive information from model systems that supports the potential efficacy of the lead agent or medical device in humans. In addition, applications must describe a statistical/analytical plan to support the proposed studies, if applicable. These analyses must be consistent with current FDA guidance.

The National Cancer Institute (NCI) has constructed developmental pathways for translational research that may be useful for designing translational research studies for support under the

LCTA mechanism. These pathways are comprehensive and span the entire translational research continuum from discovery of a target to clinical trials (http://www.cancer.gov/images/trwg/Developmental-Pathway-Agent-Drug_Biologics.pdf).

PIs applying to the LCTA are required 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 either 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.

Studies proposed under this award may include, but are not limited to:

- Comparative activity testing to optimize a lead agent and/or define a single lead agent from a limited library of candidates. ***Such studies must be completed within 12 months of the start date of the award. If the studies are not completed within 12 months of award initiation, the government reserves the right to terminate the award.***
- Toxicology screening
- Pharmacokinetics (e.g., absorption, distribution, metabolism, and excretion) studies
- Pharmacodynamic studies
- Radiation dosimetry
- Testing medical devices for safety or effectiveness in preclinical systems
- Development and validation of assays and reagents required to measure biological responses and molecular endpoints of the lead agent; ***such studies may only be proposed in conjunction with lead agent development***
- Combination of the lead agent with agents already in clinical testing or practice
- cGMP production of the lead agent or medical device

Studies proposed under this award should not include:

- Target discovery
- Drug screening
- Early development of medical devices
- New combinations, formulations, or modifications of agents already in clinical testing or practice (other than in combination with the lead agent)
- Mechanism of action studies
- Prevention agents

The preclinical drug or medical device development process may require resources beyond those available at a single laboratory or organization. As such, the PI must disclose within the application any patents issued or pending and/or licenses granted and/or pending, with respect to the lead agent or medical device as well as any known patents that may block the development of the lead agent or device. The PI must provide documentation, such as a Material Transfer Agreement, of access to and permission to use all intellectual and material property. Participating organizations must be willing to resolve potential intellectual and material property issues and to remove organizational barriers that might interfere with the cooperation necessary to ensure that the proposed studies can be completed.

PIs are expected to abide by the FDA existing and proposed guidance governing the conduct of preliminary studies and the collection of data in support of an IND and IDE application (refer to http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm) and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046706.htm).

Projects involving human subjects or human anatomical substances will be supported only if they are exempt under Title 32 of the Code of Federal Regulations Section 219.101(b) (4) (32 CFR 219.101(b) (4)) or qualify for expedited review under 32 CFR 219.110 or 21 CFR 56.1102. ***Clinical trials will not be supported by the LCTA. Applications proposing studies that do not qualify for exempt or expedited review status will be administratively withdrawn.*** PIs seeking funding for a clinical trial should consider submitting an application to an alternative FY12 PCRP Program Announcement/Funding Opportunity. For more information on clinical trials and clinical research overall, the "Human Subject Resource Document" is provided on the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/.

All investigators applying to FY12 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 CDMRP intends that data and research resources generated by CDMRP-funded research activities 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 an independent investigator at or above the level of Assistant Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **$1,500,000** 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.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- 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., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for the PI to attend one Department of Defense PCRP Innovative Minds in Prostate Cancer Today (IMPaCT) meeting or other similar event as directed by the CDMRP, if the meeting occurs within the period of performance of the award. The IMPaCT meeting 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. These travel costs are in addition to those allowed for annual scientific/ technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research Supplies
- Equipment
- Research-related subject costs (for studies with exempt or expedited review status only)
- Clinical research costs
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $4.8M of the $80M FY12 PCRP appropriation to fund approximately 2 Laboratory - Clinical Transition 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 multi-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 the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

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-12-PCRP-LCTA.

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/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507. A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer.

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 (COI) – Tab 3**

  FY12 PCRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk (help@cdmrp.org or 1-301-682-5507).

- **Required Files – Tab 4**

  Preproposal Narrative (three-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons needed to support the proposed study.

  The Preproposal Narrative should describe the proposed project using the following outline:

  - **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research; include relevant literature citations. Clearly describe the target, lead agent or device, and mechanism of action in prostate cancer.
  - **Hypothesis or Objective:** State the hypothesis to be tested and/or the objective(s) to be reached.
  - **Research Approach:** State the project's specific aims and briefly describe the experimental approach to accomplishing the aims. ***This award cannot be used to conduct clinical trials.***
  - **Impact:** Describe the potential short-term and long-term impact of this study on prostate cancer research and/or patient care. Briefly describe how the proposed study is responsive to one of the PCRP overarching challenges or, alternatively, provide a description to justify how the project will nevertheless address a critical need in prostate cancer clinical care.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

- References Cited (one-page limit): List 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). The inclusion of Internet URLs to references is encouraged.
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Key Personnel Biographical Sketches (two-page limit per individual).

- **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.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the Department of Defense (DoD) and the PCRP, pre-applications will be screened by the PCRP Integration Panel (IP) based on the criteria shown below, which are of equal importance.

  - **Intent of the Award Mechanism:** To what degree the lead agent or medical device is sufficiently developed so that the award will effectively bring it toward IND or IDE application and /or cGMP production.
  - **Research Approach:** To what degree the experimental approach for accomplishing the specific aims is feasible and addresses the objective.
  - **Impact:** To what degree the lead agent or medical device is responsive to the PCRP overarching challenges and has the potential to revolutionize prostate cancer research and/or patient care.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. Pre-application notification dates are indicated on the title page of this Program Announcement/ Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the PI has received notification of invitation.

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/).

Grants.gov application package components: For the Laboratory - Clinical Transition 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 (25-page limit):** Upload as "ProjectNarrative.pdf."

     Describe the proposed project in detail using the outline below. ***The inclusion of preliminary data is required.*** Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

     - **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
     - **Lead Agent or Device:** Describe the target, the lead agent or device and its clinical utility, and the mechanism of action. Indicate whether the lead agent or device is being developed in partnership with another organization, and the nature of the partnership.
     - **Objective:** State the overall objective(s) to be reached.
     - **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
     - **Research Strategy:** Describe the experimental design for preclinical validation of the lead agent or device under development. Describe in detail the methods and analyses, including appropriate controls, a timeline for the completion of each proposed task, and how the approaches are compliant with FDA guidance for IND or IDE application. Address potential problems and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***Projects involving human subjects or anatomical substances will be supported only if they are exempt or qualify for expedited review status. This award cannot be used to conduct clinical trials.***

- **Overarching Challenges and Focus Areas:** Describe how the proposed research is 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 either 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 component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present 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, reflecting the laboratory space, equipment, and other resources available for the project.
  - 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.
  - Patents and Permissions (if applicable): Disclose any patents, issued or pending, and/or licenses, granted and/or pending, with respect to the lead agent as well as any known patents that may block the development of the lead agent. The PI must provide documentation of access to and permission to use all intellectual and material property.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

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

  The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

  - Background: Present the ideas and reasoning behind the proposed project.
  - Objective: State the objective to be reached. Provide evidence or rationale that supports the objective.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design.
  - Impact: Summarize the potential impact of the proposed project on the elimination of death and suffering from prostate cancer.

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

  Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. The lay abstract is used by consumer reviewers along with other components of the application package.

  - 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 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?

- **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.

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

  Explain in detail why the proposed research project is important, as follows:

  Describe the short-term impact: Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research.

  Describe the long-term impact: Explain the anticipated long-term gains from the proposed research, including how the new product may ultimately contribute to the goal of eliminating death and suffering from prostate cancer.

  PCRP Overarching Challenges: Summarize how the proposed project addresses one of the PCRP overarching challenges or another critical issue in prostate cancer research and/or patient care. State explicitly how the proposed work and the lead agent or medical device to be developed will, if successful, have an impact on prostate cancer research and/or clinical care, and how the expected results of the project will contribute to the goal of eliminating death and suffering from prostate cancer.

- **Attachment 7: Transition Plan (one-page limit):** Upload as "Transition.pdf."

  Provide information on the methods and strategies proposed to move the product to clinical trial and/or delivery to market upon successful completion of the award. The transition plan should include the components listed below.

  - A description of the expected outcome(s) that will result after completion of the proposed research project. Outcomes should be specific and measurable.
  - Details of the funding strategy that will be used to bring the outcomes to clinical trial and/or delivery to market (e.g., specific potential commercial partners, specific funding opportunities to be applied for, etc.).
  - A description of collaborations and other resources that will be used to provide continuity of development.
  - A brief schedule and milestones for bringing the outcome(s) to clinical trial and/or delivery to market.
  - A risk analysis for cost, schedule, manufacturability, and sustainability.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
   - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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.

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. Organizations are required to provide a Data Universal Numbering System (DUNS) number and register with the Central Contractor Registry (CCR) 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 compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DoD 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. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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, of these, Lead Agent/Device, Research Strategy, and Clinical Impact are equally the most important, with the remaining criteria listed in decreasing order of importance:

    - **Lead Agent/Device**
        - Whether the PI has identified a well-defined target, and how well the preliminary data support the validity of the target for prostate cancer.
        - To what extent the development of the lead agent or device is justified by a sound scientific rationale that is supported by a critical analysis of the relevant literature, preliminary data, and logical reasoning.
        - To what extent there is likelihood for commercial licensing of the lead agent or device.

- To what extent the PI has clearly documented, with supporting preliminary and/or published data, that the mechanism of action of the lead agent or device on the target has been established.

- **Research Strategy and Feasibility**
  - To what extent the study has the potential of developing a viable lead agent or device that would be ready for cGMP production.
  - If applicable, whether the PI has presented a clear and feasible plan to narrow a small library of potential lead agents to one lead agent within the first 12 months after award initiation.
  - How well the objectives, aims, experimental design, methods, and analyses are developed.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - Whether the proposal includes a clear and appropriately powered statistical plan.
  - How well the research strategy complies with FDA recommendations for studies in support of IND or IDE applications.
  - If applicable, whether the PI has presented an Intellectual and Material Property Plan sufficient to resolve potential issues among participating organizations, including the acknowledgement of and compliance with relevant patents and permissions.

- **Clinical Impact**
  - To what extent the lead agent or device, if successfully developed, will have a major impact on prostate cancer clinical care and the elimination of death and suffering from prostate cancer.
  - 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.

- **Transition Plan**
  - Whether a well developed plan for bringing the product to clinical trials or delivery, including potential funding strategies, was described.
  - To what extent the expected outcome(s) that will result after completion of the proposed research project are specific and measurable.
  - Whether plans for appropriate collaborations and other resources for providing continuity of development were well described.
  - To what extent the schedule and milestones for bringing the outcome(s) to clinical trial and/or delivery to market are appropriate.
  - Whether an appropriately developed potential risk analysis for cost, schedule, manufacturability, and sustainability was provided.

- **Personnel**
    - To what degree the research team's background and prostate cancer-related expertise are appropriate with respect to its ability to perform the proposed work.
    - To what degree the levels of effort are appropriate for successful development of the lead agent.
    - Whether letters of collaboration are provided for any proposed collaborative arrangements (if applicable).

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

- **Environment**
    - To what degree the scientific environment is appropriate for the proposed research.
    - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
    - To what degree the quality and extent of organizational support are appropriate.
- **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 determine the application's relevance to the mission of the DoD and PCRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
    - Adherence to the intent of the award mechanism
    - Programmatic relevance in relation to the PCRP overarching challenges and focus areas
    - Ratings and evaluations of the peer reviewers
    - Relative impact
    - Program portfolio composition

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

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 scientific peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- 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 and Preproposal 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 pre-application or application:

- A FY12 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 FY12 PCRP IP members can be found at http://cdmrp.army.mil/pcrp/panels/panel12.
- 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.
- The application includes a clinical trial or human subject studies that do not qualify for exempt or expedited review status.
- 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 U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/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, 2013. 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

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

D. Award Transfers

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: 1-301-682-5507

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: 1-800-518-4726

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. 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 Transition Plan (Transition.pdf) as Attachment 7.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI 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 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.	