Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Laboratory-Clinical Transition Award

Funding Opportunity Number: W81XWH-11-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)**,** June 10, 2011
- **Invitation to Submit an Application:** July 13, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, September 1, 2011
- **Scientific Peer Review:** October 2011
- **Programmatic Review:** December 2011

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Prostate Cancer Research Program (PCRP) was established in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY10 totaled $1.05 billion. The FY11 appropriation is $80 million (M).

The overall goal of the FY11 PCRP is to find and fund innovative, high-impact research that will eliminate death and suffering from prostate cancer. Specifically, the PCRP seeks to support innovative, high-risk, high-gain research with potential near-term impact; sponsor multidisciplinary synergistic research; fund translational studies to promote the fluid transfer of knowledge between bedside and bench; invest in research on patient survivorship (quality of life); foster the next generation of prostate cancer investigators through mentored research; and promote research into prostate cancer health disparities.

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 relapse with no available curative therapy)
- Distinguish aggressive from indolent disease

PCRP Focus Areas *(revised for FY11)*

All applications for FY11 PCRP funding opportunities should also address at least one of the following PCRP focus areas:

Biomarkers: Discovery and validation of biomarkers for the detection, prediction of response to therapy, prognosis, and progression of prostate cancer.

Genetics: Understanding the genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for clinically significant prostate cancer.

Imaging: Development of new anatomic and molecular imaging technology for the detection and management of prostate cancer.

Survivorship: Studies on the impact of treatment, nutrition, metabolism, and exercise on the well-being of prostate cancer patients and their families.

Therapy: Identification of new targets, pathways, and therapeutic modalities, including immunotherapy and mechanisms of resistance.

Tumor Biology and Immunology: Understanding prognosis and progression of prostate cancer.

B. Award Information

The PCRP Laboratory-Clinical Transition Award mechanism was introduced in FY07. Since then, 49 applications have been received, and 9 have been recommended for funding.

The Laboratory-Clinical Transition Award supports product-driven preclinical studies of promising lead agents 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 to human testing. The goal of this award is the generation of pharmacology and toxicology data for inclusion in a U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) application and/or ***(new for FY11)*** current Good Manufacturing Practice (cGMP) production of the lead agent(s). Agents supported by this award mechanism 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) showing how the product will progress to clinical trials and/or delivery to market after the completion of the PCRP award.

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(s) on the target. ***Lead agents are defined as novel biological, molecular, or chemical therapeutics or imaging agents, that have potential clinical application to prostate cancer.*** Examples of lead agents include, but are not limited to: novel chemotherapeutics, antibodies, nanoparticles, and imaging contrast agents.

Applications must include preliminary data relevant to the lead agent(s) under development. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team. 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(s) in humans. In addition, applications must describe a statistical/analytical plan(s) to support the proposed studies. 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 this 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).

All applications for the Laboratory-Clinical Transition Award are highly recommended to address one of the FY11 PCRP overarching challenges. The PCRP seeks to fund projects from the wide spectrum of basic to clinical research; however, if the proposed project does not address one of the overarching challenges, the application should provide 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/efficacy 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
- 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

Studies proposed under this award should not include:

- Target discovery
- Drug screening
- Development of 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 development process may require resources beyond those available at a single laboratory or organization. As such, the PI must disclose any patents issued or pending, and/or licenses granted and/or pending, with respect to the lead agent(s) as well as any known patents that may block the development of the lead agent(s). 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 application (refer to http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm).

Projects involving human subjects or 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 are not allowed. A clinical trial is defined as a prospective accrual of human

subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical research, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/. Additional information on the protection of human subjects and exempt or expedited review status may be found at https://www.bids.tswg.gov/. ***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 for the FY11 PCRP Clinical Trial Award.

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 amount for the entire period of performance is **$750,000** 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 form. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel to one 3½-day PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting, which is held to disseminate the results of PCRP-sponsored research.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment

- Clinical research costs (other than costs for clinical trials, which are not allowed)
- 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 $2.4M of the $80M FY11 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 discouraged. The Government reserves the right to 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-11-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 a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507. Changes 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**
- **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.

  The Preproposal Narrative should include the following:

  - **Background/Rationale:** Clearly articulate the ideas and reasoning behind the proposed research; include relevant literature citations. Clearly describe the target, lead agent(s), and mechanism of action in prostate cancer.
  - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Research Strategy:** Concisely describe the project's specific aims.
  - **Clinical Impact:** Describe the potential of the proposed study to have a revolutionary impact towards eliminating death and suffering from prostate cancer.
  - **Overarching Challenges and Focus Areas:** Describe how the proposed study is responsive to one of the PCRP overarching challenges. If the proposed project does not address at least one of the overarching challenges, provide a description to justify how the project will nevertheless address a critical need in the field of prostate cancer research and/or patient care. In addition, state at least one of the PCRP focus areas to which the proposed study is responsive.

  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.
  - Biographical Sketches for the PI and Key Personnel (four-page limit per individual)

- **Submit Pre-application – Tab 5**

- **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 CDMRP, pre-applications will be screened by the PCRP Integration Panel (IP). PIs whose pre-applications meet the intent of the award mechanism will be invited to submit applications.

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

  Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; 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 a letter 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 (AOR) 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 relevant to the target, lead agent, and mechanism of action is required.*** Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

     The Laboratory-Clinical Transition Award supports research from the identification of a lead agent through cGMP production of the agent.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
- **Target and Lead Agent(s):** Describe the target, the lead agent(s) and its clinical utility, and the mechanism of action of the agent on the target. Indicate whether the lead agent(s) are 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(s) 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 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. ***This award may not be used to conduct clinical trials.***
- **Overarching Challenges and Focus Areas:** Describe how the proposed study is responsive to one of the PCRP overarching challenges. If the proposed project does not address at least one 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. In addition, state at least one of the PCRP focus areas to which the proposed study is responsive.

- **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. ***Each component has no page limit unless otherwise noted.***
  - 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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they must be included. 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(s) as well as any known patents that may block the development of the lead agent(s). 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. Include material transfer agreements (MTAs) or MTA requests, if applicable.

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

  Describe the proposed research project, including the following elements: Background, Objective/Hypothesis, Study Design and Specific Aims, and Impact. 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.

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

  Public abstracts should be written using the outline below. Do not duplicate the technical abstract. The public 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.

  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 understanding 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 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, measurable, and should include a definition of the end user.
  - 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 industry 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 the military or civilian market.
  - A risk analysis for cost, schedule, manufacturability, and sustainability.

3. **Research & Related Senior/Key Person Profile (Expanded) Form:** 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 shall 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 Number 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, USAMRMC, based on technical merit, the relevance to the mission of the DOD and CDMRP, 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 meritbased 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, it is a crime for Federal officials to disclose confidential information of one party to another third party (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(s), Research Strategy, and Clinical Impact are the most important, with the remaining criteria listed in decreasing order of importance.

- **Target, Lead Agent(s), and Mechanism of Action**
  - 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(s) is justified by a sound scientific rationale that is supported by a critical analysis of the relevant literature, preliminary data, and logical reasoning.
  - Whether there is apparent likelihood for commercial licensing of the lead agent.
  - To what extent the PI has clearly documented, with supporting preliminary and/or published data, that the mechanism of action of the lead agent(s) on the target has been established.
- **Research Strategy and Feasibility**
  - Whether the study has the potential of developing a viable lead agent 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 nonclinical studies in support of IND submissions.
  - 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(s), 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. Also, whether the end user of the outcome(s) was well defined.
  - 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(s).
  - 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 CDMRP, 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
    - 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. PIs 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:

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

- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

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, you 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:

- FY11 PCRP IP member is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY11 PCRP IP members may be found at http://cdmrp.army.mil/pcrp/panels/panel11.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- 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 and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The application includes 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 US 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, 2012. 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 C, for general information regarding administrative and national policy requirements.

C. Reporting

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

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, 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 and 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 Public Abstract (PublicAbs.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 form 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.	