

Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Transformative Impact Award

Funding Opportunity Number: W81XWH-12-PCRP-TIA

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, Stage 1:** December 2012
- **Invitation for Oral Presentation:** December 2012
- **Programmatic Review, Stage 2:** January 2013

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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, including immunotherapy and mechanisms of resistance.

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

B. Award Information

The PCRP Transformative Impact Award supports prostate cancer research with near-term clinical relevance that will *transform and revolutionize* the clinical management of prostate cancer, to include the wide spectrum of screening, detection, diagnosis, prognosis, and/or treatment), and have a major impact on the elimination of death and suffering from prostate cancer.

Although research that is deemed transformative must contend with potential risks, the proposed project(s) must be supported by thorough review of the literature, and sound rationale and well-designed research strategy. Applications must include substantive preliminary data to support the rationale and feasibility of the study. The critical components of this award mechanism are:

Research Scope: Since the intent of this award is to achieve near-term clinical impact in patients, the scope of the research effort is expected to include translational research, clinical research, and/or clinical trials. *All PIs are strongly encouraged to propose projects for this award that address one the PCRP overarching challenges and at least one of the PCRP focus areas.*

Transformative Impact: Projects funded by this award will have a near-term, *revolutionary* impact on the clinical management of prostate cancer. It is the responsibility of the Principal Investigator (PI) to clearly and sufficiently describe how the proposed project(s) will transform prostate cancer clinical management in the near term.

Implementation Plan: The project(s) must be supported by a detailed plan that identifies critical milestones, outlines the knowledge, expertise, and technical innovations that the investigative team will utilize to achieve the milestones, and explains how the outcomes of the project(s) will be translated to patients. The application must include information demonstrating accessibility and availability of human subjects, substances, and/or data necessary for the study so that the project(s) can commence immediately after an award is made. PIs whose study designs require human anatomical substances are encouraged to collaborate with personnel affiliated with established prostate cancer biorepositories (e.g., Prostate Cancer Biorepository Network [PCBN] [<http://www.prostatebiorepository.org>] and/or the North Carolina - Louisiana Prostate Cancer Project [PCaP] [<http://www.ncla-pcap.org>]). A robust statistical plan and statistical expertise should be included where applicable in proposed investigation(s).

Research Team: It is expected that the proposed research team will include an exceptionally skilled group of individuals (e.g., scientists, clinicians, consumer advocates, etc.) well positioned to realize the goals, with leadership from multiple collaborators. The PI should possess a track record of success in leading large, focused projects with clinical impact. The PI also should demonstrate a strong commitment to the project and to the research team, and develop a communications plan that fosters consistent and intensive interactions by all team members to accelerate translation of the project's outcomes to patients and/or for clinical use.

Oral Presentation: Due to the nature of the Transformative Impact Award, an oral presentation to the PCRP Integration Panel (IP) is a requirement for application review as described below:

- **Programmatic Review, Stage 2:** A PI whose application is selected for final consideration in Stage 2 of the Programmatic Review will be required to give an oral presentation that will be held in the Washington, DC area in January 2013.

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local IRB of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the local IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

The Congressionally Directed Medical Research Programs (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 **\$6,000,000** 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 and up to two members of the research team to attend a 1-day meeting to be held in the Washington, DC area during the award period of performance. This meeting will be held to provide a presentation on progress and discuss emerging research ideas. Costs associated with travel to this meeting, up to \$1,800 per person, should be included in Year 2 of the budget.
- Travel for the PI and up to four additional members of the research team to attend one DoD 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 per person, 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
- Research-related subject costs
- Clinical research costs
- Purchase of datasets and/or databases
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to five individuals among the PI and key personnel (maximum of \$1,800 per year per person) to attend scientific/technical meetings

The CDMRP expects to allot approximately \$19.2M of the \$80M FY12 PCRP appropriation to fund approximately two Transformative Impact 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-TIA.

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 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(s) using the following outline:

- **Background/Rationale:** Present the ideas and reasoning behind the proposed research; include relevant literature citations.
 - Describe the problem or question in prostate cancer that will be the focus of the proposed project(s).
 - Describe the approach to develop a solution for the problem or question.

- **Impact:** Describe the intended outcome of the proposed project(s) on the clinical management of prostate cancer and how the impact would be highly transformative.
- **Hypothesis(es) or Objective(s):** State the hypothesis(es) to be tested or the objective(s) to be reached. Clearly describe how the research question addresses one of the PCRCP overarching challenges.
- **Research Approach:** State the project's specific aims and concisely describe the experimental approach for accomplishing the aims.
- **Research Team:** Describe the composition, expertise and organization of the research team and each team member's role in the project(s), with additional emphasis on the leadership role of the PI. Briefly describe how these features will facilitate the success of the key aspects the project(s).

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 DoD and the PCRCP, pre-applications will be screened based on the following criteria:

- **Intent of the Award Mechanism:** To what degree the proposed research, if successful, will make a highly *transformative* impact on eliminating death and suffering from prostate cancer through major improvements to prostate cancer clinical management in the near-term.
- **Research Approach:** Whether the research approach appears feasible and appropriately designed to accomplish the aims of the project(s).

- **Personnel:** To what degree the background and prostate cancer-related expertise of the PI and key personnel are appropriate with respect to their abilities to successfully complete the proposed work, and the extent to which the PI appears well prepared and committed to lead the proposed project(s) toward clinical impact.
- **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/>). For the Transformative Impact Award, additional application components are also required and should be submitted as directed below.

Grants.gov application package components: For the Transformative Impact 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(s) in detail using the outline below. Throughout the Project Narrative, clearly convey how the proposed research, if successful, would transform the clinical management of prostate cancer and/or change clinical practice, and ultimately advance the goal of eliminating death and suffering from prostate cancer.
 - **Background:** Present the ideas and reasoning behind the proposed research and include a literature review, preliminary studies and/or preclinical data that led to the development of the proposed project(s); unpublished preliminary data should originate from the laboratory of the PI or members of the research team named on this application.
 - **Hypothesis:** State the hypothesis(es) to be tested or the objective(s) to be reached.
 - **Specific Aims:** Explain the project’s specific aims.

- **Research Strategy:** The research strategy should be based on sound scientific rationale, outlined in detail, and fully supported by the preliminary data and published reports. Describe the experimental design, methods, and analyses. Include a description of appropriate controls and endpoints to be tested, if applicable. Address potential problem areas and present alternative methods and approaches. Statistical analyses appropriate to the type of study (e.g., power analysis for population-based studies) should be well described in sufficient detail for evaluation.

If a prospective clinical study is proposed, discuss the strategy for initiating the study early in the first year of the award. Provide a properly powered statistical plan and information demonstrating how a sufficient number of human subjects or human anatomical substances will be accrued to the proposed study during the award period. *Include a clear and detailed description of the potential ethical issues raised by the proposed study, and provide a detailed plan for how the ethical issues will be addressed.* The study personnel must demonstrate appropriate expertise in conducting clinical studies.

- **Implementation Plan:** Provide an overall strategic plan for completing the proposed project(s) that identifies critical milestones; outlines the knowledge, expertise, and technical innovations that the investigative team will utilize to make decisions, allocate resources, and accomplish the milestones; and explains how the outcomes of the project(s) will be translated to patients. Describe and/or provide evidence that the research can be initiated without delay once the award is made.
 - **Research Team and Environment:** Describe how the PI's research experience, leadership skills, and commitment to making a revolutionary impact for prostate cancer patients make him/her well qualified to coordinate this collaborative effort. Discuss the qualifications of the research team, their specific contributions to the project(s) and how the appropriate expertise is necessary to address the research question and enable the success of the proposed project(s). Describe the research environment(s) and how the facilities and resources will support the research requirements and the collaborative project(s). Present an overall management plan to facilitate consistent and intensive interactions by all team members in the project(s), including aspects such as communications, data sharing, adherence to regulatory requirements, administrative support, and oversight to accelerate translation of the project's outcomes to patients and/or for clinical use.
 - **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(s).
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that describes how he/she will support the project(s), to include:
 - Unique expertise,
 - Availability and access to research resources, and/or
 - Availability of and access to appropriate populations (and/or access to available samples/data or database[s]) (if applicable).
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
 Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers; however, programmatic reviewers do not typically 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(s).
 - Objective(s)/Hypothesis(es): State the objective(s)/hypothesis(es) to be studied.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design including appropriate controls.
 - Clinical Impact: Briefly summarize how the proposed project(s) may lead to a near-term, transformative impact on the clinical management of 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(s) and rationale for the proposed project(s) 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 how the proposed research project is important, as follows:
 Detail the anticipated results/outcome(s)/product(s) that will be directly attributed to the results of the proposed research. Explain how these results/ outcome(s)/ product(s) will be transformative on the clinical management of prostate cancer. Describe the benefits to be realized and how rapidly they will be successfully translated to patients.

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.

Additional Application Components: In addition to the completed Grants.gov application package of forms and attachments, Transformative Impact Award applications also require the following components:

Oral Presentation: PIs whose applications are selected during Programmatic Review, Stage 1, for final consideration in Programmatic Review, Stage 2, will be required to give an oral presentation that will be held in the Washington, DC area in January 2013.

Each presentation will include a 10-minute talk by the PI, followed by a 20-minute question and answer session with IP members. Time limits will be strictly enforced. The oral presentation should not be used to reiterate the technical/scientific details of the project(s) already described in the written application. Rather, the following questions will be the topics for discussion during the PI’s talk and the question and answer session. A PI who is invited must prepare a presentation that specifically addresses these questions:

- Without addressing your specific project(s), what barriers do you consider are the most urgent to overcome in the clinical management of prostate cancer?
- How will your new approach have a transformative impact on the clinical management of prostate cancer and the elimination of death and suffering from prostate cancer?
- How will you use your leadership skills to create an environment that fosters creativity and succeed in rapidly translating research outcomes to the clinic?

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, 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, which are of equal importance:

- **Impact**
 - To what degree the potential gains of the proposed project(s):
 - Will be near-term and
 - Will be transformative in the clinical management of prostate cancer.
 - To what degree the transformative outcomes of the proposed research will contribute to the elimination of death and suffering from prostate cancer.
 - How well the project(s) addresses one or both of the PCRP overarching challenges.

- **Research Strategy and Feasibility**
 - How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and logical reasoning.
 - How well the hypotheses or objectives, aims, clinical and other appropriate endpoints (as applicable), experimental design, methods, and analyses are developed and integrated into the project(s).
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - Whether the application includes an appropriate statistical plan with power analysis (if applicable).
 - Whether the PI has provided sufficient evidence to support availability and accessibility of the populations/samples required for the study (if applicable).

- **Implementation Plan**
 - How the proposed project(s) is supported by a detailed plan that identifies critical milestones and explains how these milestones will be achieved.
 - Whether the proposed plan is appropriate with respect to plans for decision-making, allocation of resources, consistent interaction and coordination of personnel and collaborations, including regulatory approval processes, and conflict resolution among all participating PIs and institutions.
 - For clinical studies, whether the PI has sufficiently demonstrated that the research can be initiated early in the first year of the award (e.g., with appropriate consideration for regulatory approvals, etc.).

- **Personnel**
 - To what degree the PI has provided convincing evidence of his/her abilities and commitment to successfully lead the research team in achieving the outcome of transformative, revolutionary impact from the proposed project(s).

- To what degree the research team’s background and expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient expertise for all aspects of the work, and whether there is evidence of strong commitment to the project(s).
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- **Environment**
 - To what degree the scientific environment(s) is appropriate for the proposed research.
 - How well the research requirements are supported by the availability and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements).
 - To what degree the quality and extent of organizational support are appropriate for the proposed research.

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

- **Ethical and/or Regulatory Issues**
 - If applicable, whether there is evidence that the PI and research team have appropriately considered and developed a plan to address potential ethical issues (e.g., informed consent, information privacy, assessment of risk versus benefit of participation) raised by the proposed study.
- **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:

- **Stage 1:** During the first stage of programmatic review, applications will be selected for the second stage using the following criteria:
 - 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
- **Stage 2:** During the second stage of programmatic review, the following criteria will be used:
 - Understanding of critical issues/barriers in prostate cancer clinical management such that the PI and collaborators have appropriately selected projects best suited to address the issues;
 - Articulation of an approach with high likelihood for transformative impact; and
 - Leadership capability to create an environment that fosters creativity and rapid translation of outcomes into clinical use/practice.

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 PCRIP 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 PCRIP 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 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

Recipients of this award will be required to present an update on progress toward accomplishing the goals of the project(s) at a 1-day meeting to be held in the Washington, DC area during the award period of performance. In addition to progress reporting, it is anticipated that the meeting will provide an opportunity to discuss additional ideas that, due to the nature of the Transformative Impact Award, are generated during the conduct of the award and could be rapidly translated to patients and/or clinical use. These discussions may be relevant to future PCRP funding opportunities, contingent on receipt of Congressional appropriations in future fiscal years.

For all awards including prospective accrual of human subjects, quarterly technical progress reports will be required.

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

D. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

The transfer of an award to another institution is strongly discouraged. A transfer will not be allowed for any institution that includes a study site/clinical trial at its location. Approval of a transfer request from an institution that does not include a study site at its location will be 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.

E. Pre-Award Meeting

At the Government's discretion, the PI and key personnel may be requested to participate in a pre-award meeting at the Government's expense.

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.	
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.	
Additional Application Components	Action	Completed
Oral Presentation	Confirm availability to give an oral presentation in the Washington, DC area in January 2013 (if selected for Programmatic Review, Stage 2).	