

# **Program Announcement**

**for the**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Prostate Cancer Research Program**

### **Clinical Consortium Award**

**Funding Opportunity Number: W81XWH-13-PCRP-CCA**

**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), September 18, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 9, 2013
- **Peer Review:** December 2013
- **Programmatic Review:** March 2014

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

## TABLE OF CONTENTS

|   |           |
|---|-----------|
| <b>I. Funding Opportunity Description .....</b>         | <b>3</b>  |
| A. Program Description .....                            | 3         |
| B. Award Information.....                               | 4         |
| C. Eligibility Information .....                        | 10        |
| D. Funding .....  | 10        |
| <b>II. Submission Information .....</b>                 | <b>13</b> |
| A. Where to Obtain the Application Package.....         | 13        |
| B. Pre-Application Submission Content and Form .....    | 13        |
| C. Application Submission Content and Form .....        | 14        |
| D. Submission Dates and Times .....                     | 23        |
| E. Other Submission Requirements.....                   | 23        |
| <b>III. Application Review Information.....</b>         | <b>23</b> |
| A. Application Review and Selection Process.....        | 23        |
| B. Application Review Criteria .....                    | 24        |
| C. Recipient Qualification .....                        | 27        |
| D. Application Review Dates .....                       | 28        |
| E. Notification of Application Review Results .....     | 28        |
| <b>IV. Administrative Actions .....</b>                 | <b>28</b> |
| A. Rejection .....                                      | 28        |
| B. Modification.....                                    | 28        |
| C. Withdrawal.....                                      | 28        |
| D. Withhold .....                                       | 29        |
| <b>V. Award Administration Information .....</b>        | <b>29</b> |
| A. Award Notice .....                                   | 29        |
| B. Administrative and National Policy Requirements..... | 29        |
| C. Reporting.....                                       | 29        |
| D. Award Transfers.....                                 | 30        |
| E. Pre-Award Meeting.....                               | 30        |
| <b>VI. Agency Contacts .....</b>                        | <b>30</b> |
| A. CDMRP Help Desk.....                                 | 30        |
| B. Grants.gov Contact Center.....                       | 30        |
| <b>VII. Application Submission Checklist .....</b>      | <b>31</b> |

## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

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

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

#### **PCRP Overarching Challenges** (*revised for FY13*)

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

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

#### **PCRP Focus Areas** (*revised for FY13*)

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

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

- **Imaging:** Development of new anatomic, functional, and molecular imaging approaches for the detection and management of clinically relevant prostate cancer
- **Mechanisms of Resistance:** Understanding primary and acquired resistance to therapy
- **Survivorship and Palliative Care:** Improving the quality of life and well-being of prostate cancer patients and their families
- **Therapy:** Identification of new targets, pathways, and therapeutic modalities
- **Tumor and Microenvironment Biology:** Understanding the intrinsic and extrinsic mechanisms contributing to tumor development and the progression of prostate cancer

## B. Award Information

The PCRP Clinical Consortium Award (CCA) mechanism was previously offered in FY05, FY06, and FY08. Overall, 38 Clinical Consortium Award applications have been received, and 24 have been recommended for funding.

The Clinical Consortium Award provides the support to develop and enhance collaborations and resources necessary for a network of organizations to rapidly execute Phase II or Phase II-linked Phase I (Phase I/II) prostate cancer clinical trials. These trials will include investigations of high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer, especially as pertaining to the FY13 PCRP overarching challenges. Support from this award is directed toward consortium infrastructure needs rather than direct support of the research itself. In accordance with PCRP goals, the conduct of Phase I/II trials that incorporate investigations of biomarkers for risk assessment, early detection, prediction of aggressiveness, and/or progression of prostate cancer is particularly encouraged.

The principal goal of the Clinical Consortium Award is to combine the efforts of leading investigators to bring to market high-impact, novel therapeutic interventions that will ultimately and significantly decrease the impact of the disease. To facilitate global investigations, Principal Investigators (PIs) from both U.S. and international institutions are encouraged to apply. Submissions from institutions with enhanced access to patients from disproportionately affected populations are especially encouraged.

The consortium will consist of approximately 10 Clinical Research Sites and one Coordinating Center. ***NEW for FY13: In addition, the consortium will include two or more Affiliate Clinical Research Sites to be selected and supported by the Coordinating Center.*** The Coordinating Center and Clinical Research Sites will be jointly responsible for proposing, selecting, and conducting Phase II and Phase I/II clinical trials focused on prostate cancer therapeutic interventions. The structure of the consortium is described in detail below.

The PCRP Clinical Consortium Award mechanism will be used to select and fund both the Coordinating Center and the Clinical Research Sites. PIs will be required to indicate whether the institution is applying as either the Coordinating Center with a Clinical Research Site or as a Clinical Research Site only. PIs applying as the Coordinating Center, if not selected for funding, have the option to still be considered as a Clinical Research Site only.

The Coordinating Center, in addition to functioning as a Clinical Research Site, will serve as the consortium information and planning nexus providing administrative, operational, and data management support services to participating Clinical Research Sites to implement consortium clinical trials in a timely manner. Responsibilities of the Coordinating Center will include the clinical trial selection process, protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, and intellectual/material property coordination. The Coordinating Center will also be responsible for preparing two clinical trials, with funding already secured, to be initiated by the consortium within the first 3 months of the performance period. All sites (Clinical Research Sites and the Coordinating Center) will be required to participate in at least one of these two initial clinical trials.

Collectively, the Coordinating Center PI and Clinical Research Site PIs will constitute the Clinical Consortium Committee (CCC), which will collaboratively develop and maintain a procedure for the selection of clinical trials to be implemented within the consortium. A representative from the PCRCP must be invited to meetings of the CCC as well as any other formal meetings of the consortium. All sites will be responsible for working collaboratively to identify new clinical trials for implementation. Any site may serve as an entry point for clinical trials that originate from outside the consortium. The Coordinating Center will be responsible for facilitating this entire process. The consortium is strongly encouraged to leverage the Department of Defense (DoD) investment whenever possible by implementing DoD-funded trials.

Key requirements of the Clinical Consortium Award include:

- 1. Responsibilities of the Consortium Participants:** Procedures for the consortium, while proposed by the Coordinating Center, will be fully developed and agreed upon by all participants working collaboratively. At the discretion and expense of the Government, a pre-award planning meeting may be required.
  - a. Coordinating Center:** Responsibilities specific to the Coordinating Center include:
    - Adherence to the responsibilities delineated below for a Clinical Research Site.
    - Development and maintenance of the consortium organizational structure.
    - Development and execution of plans to select and incorporate no fewer than two Affiliate Clinical Research Sites, which can be of U.S. or international origin, into consortium activities. The Coordinating Center will establish performance metrics for affiliate sites, which may be independent of those for full member Clinical Research Sites, and, if necessary, may change affiliate sites, with Government approval, during the award period of performance.
    - Provision of at least two initial Phase II or Phase I/II clinical trial protocols for implementation by the consortium within the first 3 months of the performance period.
    - Management of consortium-developed procedures for review, selection, and implementation of clinical trials proposed by or through consortium members.

- Establishment and management of procedures to ensure compliance with the local institutional review boards (IRBs) of all sites for the conduct of clinical trials and the protection of human subjects.
- Establishment and management of procedures for ensuring compliance with Food and Drug Administration (FDA) requirements for investigational agents, devices and procedures.
- Establishment and management of a communications plan and an ongoing communications system between the Coordinating Center and Clinical Research Sites.
- Management of consortium-developed quality assurance and quality control mechanisms for study monitoring, including:
  - On-site monitoring program.
  - Management plan for the handling, distribution, analysis, and banking of specimens and/or imaging products generated from consortium studies necessary for the conduct and analyses of clinical trials during the performance period of the award.
  - Registration, tracking, and reporting of participant accrual.
  - Timely medical review and assessment of participant data.
  - Rapid reporting and communication of adverse events.
  - Interim evaluation and consideration of measures of outcome.
- Management of consortium-developed comprehensive data collection and data management systems that addresses the needs of all sites in terms of access to data, data security, and data integrity measures.
- Development of statistical plans for all consortium clinical trials.
- Management of consortium-developed intellectual and material property issues among institutions participating in the consortium.
- Management of consortium-developed procedures for the timely publication of major findings and other public dissemination of data.
- Development and execution of a plan to establish financial independence from DoD funding by the end of the award period of performance.
- Development and execution of plans for ongoing review by the consortium's EAB, to include participation by Government representatives. EAB reviews should be conducted no less than twice yearly.

**b. Clinical Research Sites:** The responsibilities of each site include:

- If required by the Government, participation in a pre-award planning meeting with all consortium members to discuss operational features of the consortium, the requirements for progress and evaluation, and the award negotiations process.

- Full participation in the consortium, including but not limited to, clinical trial introduction and selection, patient accrual for consortium studies (to include accrual from disproportionately affected populations), data collection and timely submissions, meeting attendance, and adherence to the consortium's operating procedures.
- Presentation of clinical trials for the consortium's consideration each year. The minimum number of trials to be proposed to the consortium per year will be determined prior to award; however, each site application should discuss the site's capabilities to propose and secure funding for new trials for consortium execution.
- Meeting minimum accrual requirements, including disproportionately affected populations, as determined prior to award. Each site application should discuss the site's accrual capabilities.
- Provision for a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other Clinical Research Sites and the Supervising Clinical Research Coordinator of the Coordinating Center to expedite and guide clinical protocols through the regulatory approval processes and to coordinate patient accrual and study activities across sites.
- Implementation of the consortium's core data collection methodology and strategies.
- Compliance with consortium-developed quality assurance and quality control procedures, as appropriate, including:
  - Participation in an on-site monitoring program to be managed by the Coordinating Center.
  - Implementation of the consortium-developed management plan for acquisition, delivery, and storage of biological samples and study data.
  - Submission of appropriate data and materials to allow for verification and review of protocol-related procedures, for example, pathology, imaging techniques, surgical methods, and therapeutic use.
- Implementation of procedures established by the Coordinating Center for ensuring compliance with FDA requirements for investigational agents, as appropriate.
- Implementation of procedures established by the Coordinating Center to meet the local IRB requirements for the conduct of clinical trials and the protection of human subjects.
- Serving as a resource for the conduct of protocol-specified laboratory projects (such as tumor biology studies).
- Participation in consortium-developed procedures for the timely publication of major findings.
- Participation in consortium-developed procedures for resolving intellectual and material property issues among institutions participating in the consortium.

- Participation in ongoing review by the consortium's EAB.
- Submission of annual written progress reports and a final written comprehensive report.
- Additional responsibilities based on recommendations and guidance from the consortium EAB and USAMRMC staff.

**2. Performance Metrics:** Exercise of the options for continued performance of each participant site after the first year will be contingent upon meeting performance metrics as specified in the award agreements. The specific performance metrics must be proposed in Coordinating Center applications. *Final performance metrics, to which the Coordinating Center and Clinical Research Sites will be held accountable, will be established prior to award, in collaboration with the Government and the Clinical Research Sites recommended for funding.*

Performance metrics as proposed in Coordinating Center applications are suggested to include, but not be limited to, the following elements:

**a. Metrics for Coordinating Center performance:**

- The minimum number of trials to be completed in each 12-month period of the award period of performance.
- The minimum number of trials to be open at any given time after the first 6 months of the period of performance.
- The minimum proportion of trials to be conducted that move agents forward for additional testing (e.g., Phase III) and ultimately have the potential to change clinical practice. Note: The proposed minimum should not be so high as to compromise the consortium's ability to innovate in the conduct of prostate cancer clinical trials; consideration of an appropriate balance should be evident. The Clinical Consortium Award is not intended to support the conduct of clinical trials that test the next logical iteration of an existing treatment.
- The minimum percentage of patients from disproportionately affected populations (e.g., African Americans, populations with compromised access to health care) to be enrolled in consortium trials overall.
- The minimum level of impact on the field of prostate cancer clinical research. Note: It is acceptable for this metric to be expressed in qualitative rather than quantitative terms.
- Progress, as deemed acceptable by the Government, toward financial self-sufficiency.
- The minimum level of communications (publicity) to the wider clinical, scientific, and consumer communities to increase and maintain awareness of consortium activities.

**b. Metrics for Clinical Research Site performance:**

- The minimum number of patients each Clinical Research Site will be expected to accrue per year.

- The minimum level of Clinical Research Site participation in trials initiated by other sites.
  - The minimum number of clinical trials that each site will be expected to propose to the consortium each year.
  - The minimum percentage of patients from disproportionately affected populations (e.g., African Americans, populations with compromised access to health care) expected to be enrolled from each Clinical Research Site.
  - Timely submission of quality data as outlined by the Coordinating Center.
  - The minimum level of participation in other critical consortium activities (e.g., scientific or administrative working groups).
- 3. Affiliate Clinical Research Sites:** In addition to the Clinical Research Sites to be funded directly by this award, the consortium will include two or more Affiliate Clinical Research Sites. The inclusion of these sites is intended to enhance the impact of the consortium by enabling the participation of sites that can contribute in a capacity different than a full member Clinical Research Site and providing greater flexibility for the consortium to include additional sites that can best complement the consortium's activities at any given time throughout the period of performance. Coordinating Center applications must include a plan for the selection and support of these sites. This plan should describe the criteria for selecting the sites and should reflect consideration for increasing the breadth and depth of consortium activities with attention to unique populations or resources. This plan should also reflect an effort to facilitate consortium participation by international institutions as appropriate. *The final plan for Affiliate Clinical Research Site selection will be established prior to award and in collaboration with the Government and the Clinical Research Sites recommended for funding.*
- 4. External Advisory Board:** To ensure optimal conduct and oversight of consortium activities, the Coordinating Center will propose and develop an External Advisory Board (EAB). Coordinating Center applications must include a description of the proposed EAB members, the role of each member (e.g., scientific, business, or other type of review), evidence of agreement to serve, and plans for interaction between the EAB and consortium members, which should, at a minimum, include meetings (whether in person or other means) no less than twice yearly. Support for this interaction must be included in the proposed Coordinating Center budget.
- The Government reserves the right to require augmentation of the EAB membership prior to or during the award performance period. In addition, representatives of the PCRCP, Congressionally Directed Medical Research Programs (CDMRP), and/or the U. S. Army Medical Research and Materiel Command (USAMRMC) must be invited to participate in meetings involving the EAB. The Government reserves the right to direct the location of any in-person meeting. Support for Government participation should not be included in the proposed budget.
- 5. Plan for Financial Self-Sufficiency:** It is expected that the consortium will be financially self-sufficient (i.e., able to continue operations without further DoD support)

by the end of the award period. Coordinating Center applications must include a clear and detailed plan to achieve this goal.

6. **Past Performance (if applicable):** Applications from institutions that have previously received a PCRCP Clinical Consortium Award must include a description of the past performance of the award, including compliance with the metrics of the previous award as well as other individual contributions made to consortium activities.

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

### C. Eligibility Information

- PIs must be independent investigators at the Assistant Professor level (or equivalent) or higher at an eligible institution. Eligibility is not affected by previous receipt of a PCRCP Clinical Consortium Award.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### D. Funding

The PCRCP plans to invest \$15M in the Clinical Consortium Award over a 3-year period. A total of \$5M will be allocated from the FY13 budget to fund the first year of performance. Options will be included for continued performance in subsequent years with \$5M expected from each of the FY14–FY15 budgets to fund the options. The initial performance period of the award and each option period will be for 12 months. *Exercise of the options for continued performance is contingent on receipt of sufficient Congressional appropriations to the PCRCP in FY14–FY15 and acceptable performance by the recipients.*

The purpose of the PCRCP Clinical Consortium Award is to provide the funding to establish the necessary collaborations and resources to rapidly execute clinical trials by the consortium. This award will not fund research or development of clinical protocols.

### Coordinating Center

- The expected period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$3,600,000** plus indirect costs. These funds are for all Coordinating Center functions, administrative and clinical, and support for two or more Affiliate Clinical Research Sites as described in this Program Announcement/Funding Opportunity. The proposed Coordinating Center budget must include no less than **\$200,000 per year** (or a total of

\$600,000 over the award period of performance) for support of two or more Affiliate Clinical Research Sites.

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

### **Clinical Research Sites**

- The period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$600,000** to support each Clinical Research Site 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.

***Exercise of the options*** for continued performance for each Clinical Research Site after the first year will be contingent upon meeting the performance metrics as developed collaboratively between the Coordinating Center, Clinical Research Sites, and the Government prior to award, and upon sufficient receipt of Congressional appropriations to the PCRP for FY14 and FY15.

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

In addition, for this award mechanism, **direct costs for the Coordinating Center:**

Must be requested for:

- Travel for attendance at EAB review meetings (including costs for all appropriate personnel), to be held a minimum of two times per year. Costs should also be included for conducting these meetings.
- Travel for the PI and up to four additional members of the research team to attend a 1-day meeting to be held in the National Capital Area during the award period of performance. This meeting will be held to provide a presentation on progress. 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 two additional members of the research team to attend one DoD PCRP Innovative Minds in Prostate Cancer Today (IMPACT) meeting, which is held to disseminate the results of PCRP-sponsored research. Costs associated with travel to this meeting, up to \$1,800 per person, should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area.

The travel costs required above are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary support for personnel needed to meet the goals of the consortium, such as the PI, Consortium Clinical Research Coordinator, Administrative Assistant(s), Research Nurse(s), Statistician(s), Database Manager, and Informatics Manager
- Consortium-related meetings, teleconferences, and travel among participating investigators
- Database generation, software development, and website design
- Purchase of computers, specialized software, and specialized software licenses pertinent to Coordinating Center-specific responsibilities for use at participating institutions
- Costs related to establishing financial independence (e.g., fees for legal consultation)
- Other costs directly associated with planning and developing the consortium collaborations and resources
- Travel costs of up to \$1,800 per year per person for three individuals among the PI(s) and the key personnel to attend scientific/technical meetings in addition to the required meetings described above.

**Direct costs for Clinical Research Sites:**

Must be requested for:

- Travel for attendance at EAB review meetings (including costs for all appropriate personnel), to be held a minimum of two times per year.
- Travel for the PI and up to one additional member of the research team to attend a 1-day meeting to be held in the National Capital Area during the award period of performance. This meeting will be the venue in which the researchers provide a presentation on progress. 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 one additional member of the research team to attend one DoD PCRP Innovative Minds in Prostate Cancer Today (IMPACT) meeting, which is held to disseminate the results of PCRP-sponsored research. Costs associated with travel to this meeting, up to \$1,800 per person, should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area.

The travel costs required above are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary support for personnel needed to meet the goals of the consortium such as the PI, Clinical Research Coordinator, Research Nurse, and Data/Informatics Coordinator

- Consortium-related meetings, teleconferences, and travel among participating investigators
- Computers and general software required to participate in the consortium
- Other costs directly associated with planning and developing the consortium
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings in addition to the required meetings described above.

Cost sharing and utilization of other funding sources is encouraged.

*The CDMRP expects to allot approximately \$5.1M of the \$80M FY13 PCRP appropriation to fund approximately one Clinical Consortium – Coordinating Center and approximately 10 Clinical Consortium – Clinical Research Site 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. Options will be included for continued performance in subsequent years with approximately \$5M expected from each of the FY14–FY15 budgets to fund the options.*

## **II. SUBMISSION INFORMATION**

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

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

### **A. Where to Obtain the Application Package**

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

### **B. Pre-Application Submission Content and Form**

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

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

*When starting the pre-application, PIs should ensure that they have selected the appropriate application category:*

- Clinical Research Site, or
- Coordinating Center, or
- Coordinating Center with the option to be considered as a Clinical Research Site if the application is not selected for award as the single Coordinating Center.

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

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

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

- **Required Files – Tab 4**

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

- **Submit Pre-Application – Tab 5**

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

- **Other Documents Tab**

No additional documents are required.

### C. Application Submission Content and Form

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

**Grants.gov application package components:** For the Clinical Consortium 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 (60-page limit for the Coordinating Center plus Clinical Research Site, 20-page limit for each Clinical Research Site):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- a. **Coordinating Center: 40-page limit.** It is the PI’s responsibility to clearly articulate the ability of his or her group to serve as the consortium Coordinating Center and support the design and conduct of consortium clinical trials.

Describe the qualifications of the group and plans for the development of key features of the consortium Coordinating Center using the following general outline:

- (1) **Commitment to and Experience in Multidisciplinary and Multi-Institutional Prostate Cancer Clinical Research:** Describe previous experience and accomplishments related to the design, administration, and fiscal management of multi-institutional prostate cancer clinical trials, with particular emphasis on Phase II, of high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer. Describe previous experience with establishing communications systems and data management resources for multi-institutional projects. Reference relevant publications and submit reprints with the application. If the institution is a previous recipient of a PCRP Clinical Consortium Award, whether as Coordinating Center or Clinical Research Site, a description of the past performance of that award must be included.
- (2) **Institutional Resources:** Provide evidence of institutional commitment to provide the necessary resources needed to develop and support standardized data collection, data management and analysis, and data security and integrity for the consortium participants.
- (3) **Consortium Organizational Structure:** Provide a detailed description of the overall consortium organization, plans for ongoing communications, procedures for transference of funds, and standardized operating procedures for selection and implementation of clinical trials. The organizational structure should include the following key features:
  - Coordinating Center for administration and day-to-day management of consortium operations; developing the clinical trial selection process, protocol coordination; regulatory coordination; study management and monitoring; data collection, management, and statistics; intellectual/ material property coordination; and performance as a Clinical Research Site.

- Clinical Research Sites for conceiving, developing, and conducting clinical trials in prostate cancer, as well as serving as entry points for clinical trials from outside the consortium.
  - Clinical Consortium Committee composed of the PIs from the Coordinating Center and Clinical Research Sites, for the clinical trial selection process and for the continual development and operation of the consortium. A representative from the USAMRMC is to be invited to all official meetings for the Clinical Consortium Committee.
  - A proposed EAB for scientific review, oversight, data monitoring, and evaluation. Include a description of the proposed EAB members, the role of each member (e.g., scientific, business, or other type of review), evidence of agreements to serve, and plans for interaction between the EAB and consortium members, which should, at a minimum, include meetings (whether in person or other means) no less than twice yearly.
  - Plans for ongoing communications among Clinical Research Sites and between Clinical Research Sites and the Coordinating Center; plans should address methods for information distribution within the consortium, and how information technologies will be used to (1) facilitate routine multi-institutional communication and (2) provide ongoing communication and data sharing.
  - A proposed set of performance metrics for the Coordinating Center and for the Clinical Research Sites.
- (4) **Affiliate Clinical Research Sites:** Describe the proposed plan for selecting and supporting the affiliate sites. Include the process by which the opportunity for affiliate membership will be publicized, the criteria for selecting the sites, the approximate number of sites to be selected, how the sites will be supported, and how the sites will be brought into consortium activities. The plan should reflect consideration for increasing the breadth and depth of consortium activities, with attention to unique populations or resources, and should also reflect an effort to facilitate consortium participation by international institutions as appropriate.
- (5) **Clinical Trials Implementation:** Describe plans for coordinating the submission, review, selection, and implementation of clinical trials within the consortium.
- Outline plans for coordinating IRB submissions and approvals at participating sites.
  - Outline plans for developing procedures to ensure compliance with FDA requirements for investigational agents, as appropriate.
- (6) **Study Management and Monitoring:** Describe plans for ongoing communication among all institutions participating in the consortium.
- Include a **named** Supervising Clinical Research Coordinator who will interact with and oversee the Clinical Research Site clinical coordinators

to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites.

- Outline procedures for quality assurance, quality control, and study monitoring.
- Describe plans for the development of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from consortium-sponsored studies.

**(7) Data Management:** Outline a strategy for the development and implementation of a comprehensive data management and statistical analysis plan, including:

- Descriptions of the overall approach to data collection and management.
- A statistical plan that includes methods to monitor quality and consistency of data collection and methods to measure outcomes.
- A plan for ongoing data transfer.
- Data security and integrity measures.

**(8) Publication and Data Dissemination:** Describe plans for ensuring rapid publication and other public dissemination of data while maintaining participant privacy.

**(9) Fiscal Administration:** Describe previous experience with the financial management of multi-institutional clinical research studies. Outline a detailed strategy for achieving financial self-sufficiency of the consortium by the end of the performance period for the Clinical Consortium Award.

**(10) Two Initial Clinical Trials: Start section on a new page; 10-page limit for this section within the 40-page limit for the Coordinating Center portion.** Provide brief descriptions of two currently funded Phase II or Phase I/II prostate cancer clinical trials proposed to be implemented by the consortium within the first 3 months of the award period. It is expected that most, if not all, of the patients for these studies will be accrued from within the consortium. Therefore, the two initial clinical trials must be ready to initiate patient accrual just prior to or at the initiation of the award. The proposed studies will be evaluated at both peer and programmatic reviews.

Include the following information for each of the two proposed clinical trials:

- Clinical trial title: Provide the title of each clinical trial.
- Phase: Designate the clinical trial as Phase I/II or II.
- Personnel: List the names of all personnel (including the PI) who will have significant involvement in the clinical trials; include their practice license(s) (e.g., M.D. or R.N.), highest degree(s), job title(s), and employing institution(s).

- Location of study: List all centers, clinics, or laboratories where the studies are to be conducted; include details as to how consortium Clinical Research Sites will be integrated into these trials.
- Background: Describe the rationale for conducting the study, as well as the study's relevance and applicability of findings; include descriptions of preliminary studies, Phase I results, or other findings.
- Objectives: Describe the purpose, goals, and endpoint of the study.
- Drug or device: Describe the drugs or devices to be used in the studies; include Investigational New Drug (IND)/Investigational Device Exemption (IDE) numbers, sponsors, and sources, if applicable.
- Study population: Describe the target population and the proposed sample size and provide patient accrual rate requirements.
- Protocol design: Describe the type of study to be performed (prospective, retrospective, randomized, controlled, etc.) and outline the proposed methodology.
- Funding and IRB approval status: Provide evidence of funding status of the initial clinical trial(s); describe the status of IRB approval for the initial clinical trial(s).

**b. All Sites (Coordinating Center and Clinical Research Sites): 20-page limit.**

It is the responsibility of the PI to clearly articulate the qualifications of the research team and institution to participate as a Clinical Research Site in the consortium.

Provide evidence that the research team and institution fulfill each of the following criteria for participation in the consortium:

**(1) Commitment to and experience in prostate cancer clinical research**

If the institution is a previous recipient of a PCRP Clinical Consortium Award, whether as Coordinating Center or Clinical Research Site, a description of the performance of that award must be included, with emphasis on the individual contribution of the institution to consortium activities.

- Describe the PI's commitment to prostate cancer clinical research, which may include levels of effort, funding, and interactions with consumer advocacy groups.
- Describe the PI's experience in conducting multi-institutional clinical trials that demonstrate willingness and ability to function in the consortium.
- Describe specific areas of clinical research interest, such as novel drugs, combinatorial therapy schedules, surgical interventions, imaging techniques, and immunotherapies. Include overall scope of program and demonstration of integration of basic and/or correlative science into the program.

- Provide details of ongoing or completed prostate cancer-relevant clinical trials, particularly Phase II clinical trials, with an emphasis on clinical trials that might be brought into the consortium. Reference relevant publications and submit reprints with the application.
- Describe procedures for ensuring compliance with FDA requirements for investigational agents.
- Provide evidence of willingness to resolve intellectual and material property issues.

**(2) Consortium resources**

- Include a **named** institutional Clinical Research Coordinator, who will interact with the Clinical Research Coordinators at other consortium Clinical Research Sites and the Supervising Clinical Research Coordinator at the Coordinating Center, to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites.
- Describe the available prostate cancer population (including size, age range, and clinical manifestations) and provide evidence of ability to accrue prostate cancer patients into consortium-sponsored studies. Include documentation of access to and ability to recruit patients from disproportionately affected populations.
- Provide evidence of successful multi-center clinical trial collaborations.

**(3) Institutional resources**

- Provide evidence of expertise in clinical trials within the applicant institution and describe experience in the development and conduct of prostate cancer clinical trials; as appropriate, describe any additional multidisciplinary clinical and/or laboratory expertise that could serve as the basis for the development of clinical trials by the consortium.
  - Describe the resources and expertise available for the collection and processing of specimens from consortium-sponsored studies.
  - Describe the resources and expertise for data management and maintenance of data security/confidentiality.
  - Provide evidence of institutional commitment to providing facilities and resources in the conduct of consortium operations.
- **Attachment 2: Supporting Documentation (Coordinating Center and Clinical Research Sites).** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.*

- References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patent Abstracts (five-document limit for Clinical Research Site PIs, 10 for Coordinating Center PIs): 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, confirming 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.
- Intellectual Property
  - Background and Proprietary Information (*if applicable*): All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. Identify any proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
  - Intellectual and Material Property Plan: Provide a plan for resolving intellectual and material property issues among participating organizations.

***Note: As this award supports consortium infrastructure and does not provide direct support for the clinical research, certain types of intellectual property may not be relevant to this application and need not be discussed.***
- Clinical Trial Funding and Approval Documentation (Coordinating Center PIs only): Provide documentation of funding and IRB approval status for the two initial clinical trials.

- **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. Clarity and completeness within the space limits of the technical abstract are highly important.

Describe the proposed consortium or, for Clinical Research Site applications, specific participation in the consortium including the following elements:

- Background: Present the ideas and reasoning behind the proposed effort.
- Objective/Hypothesis: State the objectives to be achieved. Provide evidence that supports the feasibility.
- Specific Aims: State the specific aims.
- Study Design: Briefly describe the types of clinical trials to be proposed for conduct by the consortium.
- Clinical Impact: Briefly describe how the proposed consortium, or participation therein, may lead to a major impact on prostate cancer clinical management.

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

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

- Describe the scientific objectives and rationale for the proposed consortium 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 an impact on the standard of care for prostate cancer?
- What are the likely contributions of this study to advancing the field of prostate cancer research?

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

- **Attachment 6: Impact Statement**

Describe how the PI and other personnel will contribute to the productive operations of the consortium and have an impact moving high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer to clinical practice.

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

- ***Describe the short-term impact:*** Detail the anticipated outcomes that will be directly attributed to the results of the proposed project, including a description of the target populations. Explain how these results/outcome(s)/product(s) will have the potential to transform prostate cancer management and change clinical practice.
- ***Describe the long-term impact:*** Explain the long-term gains from the proposed project, including how the outcomes or products will ultimately contribute to the elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.
- ***PCRP Overarching Challenges:*** Summarize how the proposed research will address *any or all* of the PCRP overarching challenges.
- **Attachment 7: Data- and Research Resource-Sharing Plan (one-page limit):** Upload as “Sharing.pdf.”

Describe how unique and/or final research data will be shared with the wider prostate cancer research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the award. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or research resource-sharing plan.

Refer to the General Application Instructions, Appendix 4, Section K, for additional information.

In preparing requested budgets, applicants may include anticipated costs associated with data- and research resource-sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community).

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information. ***Note: Some of the items in this attachment may be made available for programmatic review.***

- PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
- Key Personnel Previous/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. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization’s application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

## B. Application Review Criteria

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

a. **Coordinating Center (to be reviewed in addition to the All Sites criteria below):** All Coordinating Center applications will be evaluated according to the following criteria. Of these, Personnel, Consortium Components, and Study and Data Management are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Personnel**

- How well the PI or other key personnel have demonstrated appropriate expertise in prostate cancer and in the design and administration of multi-institutional prostate cancer clinical trials.
- Whether the PI and key personnel have previous success in acquiring funding for clinical trials.
- Whether the Supervising Clinical Research Coordinator, who will interact with all Clinical Research Coordinators, possesses the appropriate expertise to coordinate regulatory approvals and consortium activities.

- **Consortium Components**

- Whether the application includes all required consortium components (e.g., EAB, Clinical Consortium Committee, Coordinating Center, and Clinical Research Sites, including affiliates).
- How well the proposed EAB has been developed.
- Whether a plan for selection and support of Affiliate Clinical Research Sites has been included and how well it will increase the breadth and depth of the of consortium activities, with attention to unique populations or resources, and reflects an effort to facilitate consortium participation by international institutions.
- How well the components as proposed will function as an integrated unit.
- How well the proposed performance metrics for the Coordinating Center and Clinical Research Sites have been developed.

- **Study and Data Management**

- How the strategies for the development and implementation of data management and statistical plans will provide access to data, data security, and data integrity.
- Whether there is an outline of an appropriate study management plan, including plans for ongoing communication, quality control, and quality assurance.
- Whether there are appropriate plans for the development of specimen handling, distribution, analysis, and banking methods.

- Whether there are appropriate plans for rapid publication and other public dissemination of data generated by the consortium.
- Whether all relevant privacy issues have been addressed appropriately.
- **Financial Management**
  - Whether the PI and/or other key personnel have appropriate experience and expertise in fiscal administration of multisite studies, including the distribution and management of funds.
  - How well the Coordinating Center personnel demonstrate ability and commitment to achieving financial self-sufficiency of the consortium by the end of the award period.
- **Coordinating Center Two Initial Clinical Trials**
  - **Personnel (applicable if a clinical trial(s) originates from outside the Coordinating Center and key personnel have not been previously listed)**
    - Whether the PI and other key personnel in the clinical trial have been named and whether they have the appropriate expertise in prostate cancer.
    - Whether the PI has a proven record of success in completing clinical trials.
  - **Study Design**
    - Whether the trials are focused on potentially high-impact, novel, therapeutic interventions.
    - Whether the study population has been adequately described.
    - Whether the investigational drugs or devices have been adequately described.
    - If from outside the Coordinating Center, whether the initiating institution(s) possess the appropriate qualifications.
    - Whether the proposed timelines indicate increased efficiency as a result of consortium participation.
  - **Regulatory Process**
    - Whether the trials will be ready for initiation at a time appropriate for implementation by the consortium.
    - Whether there are appropriate plans for the coordination of IRB submissions and approvals at participating sites.
    - Whether there is an appropriate plan for developing procedures to ensure compliance with FDA regulations for investigational agents.
    - Whether the appropriate IND/IDE numbers have been provided.

- **Impact**
  - Whether the trials address an important problem in prostate cancer.
  - To what extent the intervention or device to be tested, if the study is successful, will have a significant impact on prostate cancer.
  - Whether the types of studies proposed are appropriate.
- b. All Sites (Clinical Research Sites and Coordinating Center):** All applications will be evaluated according to the following criteria, which are of equal importance.
  - **Personnel**
    - Whether the PI meets the eligibility requirements.
    - How the research team’s background and expertise are appropriate with respect to its ability to perform multi-institutional prostate cancer clinical research.
    - To what extent the research team has the ability and experience to contribute substantially to the design and conduct of consortium clinical trials.
    - Whether the named institutional Clinical Research Coordinator has the appropriate experience in guiding clinical protocols through the regulatory approval processes and the ability to foster communication with other consortium Clinical Research Coordinators.
    - Whether there are appropriate levels of effort for successful conduct of the proposed work.
    - If applicable, whether the description of past performance of a previously received PCRP Clinical Consortium Award demonstrates successful achievement of previous award metrics and other substantive individual contributions to consortium activities.
  - **Institutional Resources and Commitment**
    - Whether the institution has demonstrated appropriate commitment to working with the consortium.
    - How the PI is supported by the availability of and accessibility to facilities and resources, especially in regard to specimen collection and processing.
    - Whether the institution possesses appropriate resources and expertise for data management and maintaining security and confidentiality.
    - How well the institution has demonstrated its willingness and ability to resolve intellectual and material property issues with other institutions in the consortium.
    - Whether the institution has unique resources that may be of benefit to the consortium.

- **Participant Recruitment**
  - Whether the PI has demonstrated sufficient access to the appropriate prostate cancer patient population.
  - Whether the PI has provided sufficient evidence of access to and ability to recruit patients from disproportionately affected populations.
  - Whether the institution has proven success in recruiting patients for clinical trials.
- **Collaborations**
  - Whether the PI has demonstrated appropriate background, expertise, and success in collaborative prostate cancer clinical research.
  - How well the PI will integrate into the consortium and be a contributing member.
  - How well the PI's institution has facilitated the PI's collaborations.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

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

- a. Ratings and evaluations of the peer reviewers**
- b. Relevance to the mission of the DHP and FY13 PCRP, as evidenced by the following:**
  - Adherence to the intent of the award mechanism
  - Programmatic relevance in relation to the PCRP overarching challenges and focus areas
  - Relative impact and innovation
  - Program portfolio composition

### **C. Recipient Qualification**

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

#### **D. Application Review Dates**

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

#### **E. Notification of Application Review Results**

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

### **IV. ADMINISTRATIVE ACTIONS**

After receipt of applications from Grants.gov, the following administrative actions may occur:

#### **A. Rejection**

The following will result in administrative rejection of the application:

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

#### **B. Modification**

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

#### **C. Withdrawal**

The following may result in administrative withdrawal of the pre-application or application:

- A FY13 PCRP Integration Panel (IP) member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY13 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel13>.

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

#### **D. Withhold**

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

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

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

#### **B. Administrative and National Policy Requirements**

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

#### **C. Reporting**

Attendance is required at a 1-day meeting to be held in the National Capital Area for the purpose of reporting on progress.

At the discretion of the government, each participant site may be expected to participate in an on-site audit by the government or its designee.

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

## **D. Award Transfers**

Institution changes in the Coordinating Center or Clinical Research Sites will not be allowed for the Clinical Consortium Award mechanism.

Changes in PI are strongly discouraged and will be considered on a case-by-case basis and approved 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 Clinical Study Coordinator or other 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: 301-682-5507

Email: [help@cdmrp.org](mailto:help@cdmrp.org)

### **B. Grants.gov Contact Center**

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

Phone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

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

## VII. APPLICATION SUBMISSION CHECKLIST

| <b>Grants.gov<br/>Application Components</b>            | <b>Action</b>   | <b>Completed</b> |
|---|---|------------------|
| 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 Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.                         |                  |
|   | Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.            |                  |
|   | Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field. |                  |
| Research & Related Budget                               | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.             |                  |
| Project/Performance Site Location(s) Form               | Complete form as instructed.  |                  |
| R & R Subaward Budget Attachment(s) Form                | Complete form as instructed.  |                  |