

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Clinical Consortium Research Site Award

Funding Opportunity Number: W81XWH-16-PCRP-CCRSA

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 15, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, October 6, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, October 11, 2016
- **Peer Review:** December 2016
- **Programmatic Review:** January 2017

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

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2016 (FY16) Prostate Cancer Research Program (PCRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The PCRP was initiated in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY15 totaled \$1.45 billion (B). The FY16 appropriation is \$80 million (M).

The mission of the FY16 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 FY16*): 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, investigators are strongly encouraged to address one or more of the following FY16 PCRP overarching challenges:

- Distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer
- Develop strategies to prevent progression to lethal prostate cancer
- Develop effective treatments and address mechanisms of resistance for men with high-risk or metastatic prostate cancer
- Develop strategies to optimize the physical and mental health of men with prostate cancer

PCRP Focus Areas: All applications for the FY16 PCRP funding opportunities are also expected to address at least one of the following FY16 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 and Response:** Understanding primary and acquired resistance as well as exceptional response to therapy
- **Survivorship and Palliative Care:** Improving the quality of life and well-being of prostate cancer patients and their families
- **Therapy:** Identification of targets and pathways, and optimization (including sequencing and combination therapies) of therapeutic modalities for prostate cancer, including metastatic prostate cancer
- **Tumor and Microenvironment Biology:** Understanding the intrinsic and extrinsic mechanisms contributing to tumor development and the progression of prostate cancer

B. Award Information

The PCRCP Clinical Consortium Award mechanism was previously offered in FY05, FY06, FY08, and FY13. Overall, 57 Clinical Consortium Award applications have been received, and 35 have been recommended for funding. This year the PCRCP is offering the Clinical Consortium Research Site Award mechanism to support the inclusion of Clinical Research Sites to the existing Prostate Cancer Clinical Trials Consortium (PCCTC).

The Clinical Consortium Research Site 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 FY16 PCRCP overarching challenges. In accordance with PCRCP 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 Research Site 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 prostate cancer. To facilitate global investigations, Principal Investigators (PIs) from both U.S. and international institutions are encouraged to apply. Investigators with access to patients in the Military Health System are also encouraged to apply. *Submissions from institutions with enhanced access to patients from disproportionately affected populations are especially encouraged.*

The PCCTC currently consists of 11 Clinical Research Sites and one Coordinating Center. The Coordinating Center and Clinical Research Sites are 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. More information about the PCCTC can be found on its website (<http://pcctc.org/>).

The Coordinating Center, in addition to functioning as a Clinical Research Site, serves 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 include the clinical trial selection process, protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, and intellectual/material property coordination. All Clinical Research Sites recommended for funding will be required to participate in at least one PCCTC clinical trial during the first year of the period of performance.

Collectively, the Coordinating Center PI and Clinical Research Site PIs constitute the Clinical Consortium Committee (CCC), which collaboratively develops and maintains 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 funded through this award mechanism will be responsible for working collaboratively within the PCCTC 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 is responsible for facilitating this entire process. The purpose of the PCRCP Clinical Consortium Research Site Award is to provide the funding to establish the necessary collaborations and resources to rapidly execute clinical trials by the PCCTC, but will not fund research or the development of clinical protocols. As such, investigators are strongly encouraged to leverage DoD investments whenever possible by implementing DoD-funded trials.

Key elements of the Clinical Consortium Research Site Award include:

1. Responsibilities within the existing Consortium:

- If required by the Government, participation in a pre-award planning meeting with all Consortium members to discuss operational features of the Consortium and the requirements for progress and evaluation.
- 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. Each 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 onsite 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 U.S. Food and Drug Administration (FDA) requirements for investigational agents, as appropriate.
 - Implementation of procedures established by the Coordinating Center to meet the local Institutional Review Board 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 External Advisory Board (EAB).
 - Additional responsibilities based on recommendations and guidance from the Consortium EAB and U.S. Army Medical Research and Materiel Command staff.
- 2. Performance Metrics:** Exercise of the options for continued performance of each participant site will be contingent upon meeting performance metrics as specified in the award agreements. *Sites will be required to adhere to the performance metrics established and implemented by the FY13 PCRP Clinical Consortium Award listed below. If performance metrics change during the period of performance, they must be approved by all the members of the PCCTC and in accordance with the Government.*

The currently approved performance metrics for the PCCTC that all sites will be expected to adhere to are as follows:

- a. Patient Accrual:** Each Clinical Research Site will be expected to accrue a minimum of 25 patients per year and enroll a minimum of 5% of patients from disproportionately affected populations.
- b. Trial Submission and Consortium Participation:** Each Clinical Research site will be expected to participate in a minimum of eight trials initiated by other sites

over 4 years; propose a minimum of two trials per year or eight trials over 4 years; and serve as a CCC member and participate in at least one committee.

- c. **Scientific Impact:** A minimum of 20% of Consortium trials will be expected to move an agent forward for additional testing.
 - i. Trials must address at least one of the PCRCP Focus Areas
 - ii. PIs will be required to describe the proposed trial's potential **impact on the field of prostate cancer clinical research** as part of the trial submission process
 - d. **Data:** To ensure timely submission of quality data, Clinical Research Sites will be expected to enter data via electronic data capture (EDC) on average less than 21 calendar days from subject site; respond to queries on average less than 14 calendar days from the time they are generated by the Coordinating Center; and have less than 1% critical and less than 5% non-critical error rates in audits conducted by Site or Coordinating Center staff.
3. **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 information, 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. Eligibility is not affected by previous receipt of a PCRCP Clinical Consortium Award.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. *If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or*

Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The PCRCP plans to invest \$800,000 in direct costs (plus indirect costs) per Clinical Research Site over a 4-year period. A total of \$200,000 in direct costs (plus indirect costs) will be allocated from the FY16 budget to fund the first year of performance for each Site. Options will be included for continued performance in subsequent years with \$200,000 direct costs (plus indirect costs) expected from each of the FY17–FY19 budgets to fund the option years. 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 FY17–FY19 and acceptable performance by the recipients.***
- The maximum period of performance is **4** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$800,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$800,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

For this award mechanism, direct costs 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 as required by the current Coordinating Center award.
- 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.

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 participating in the Consortium

- Travel costs for up to two investigator(s) to travel to two scientific/technical meetings per year. ***The Government reserves the right to direct the selection of one of these meetings, should a PCRFP-sponsored meeting be convened during the award period of performance.***
- Cost sharing and utilization of other funding sources is encouraged

Shall not be requested for:

- Clinical trial costs
- Equipment
- Research supplies

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

The CDMRP expects to allot approximately \$2.6M of the \$80M FY16 PCRFP appropriation to fund approximately eight Clinical Consortium 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.

II. SUBMISSION INFORMATION

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(s).

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-PCRP-CCRSA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.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@eBRAP.org or 301-682-5507.

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

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
 - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “*Add Organizations to this Pre-application.*” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Tab 3 – Collaborators and Key Personnel**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - FY16 PCRFP Programmatic Panel members should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
 - To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- **Tab 4 – Conflicts of Interest**
 - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C of the General Application Instructions for further information regarding COIs.
- **Tab 5 – Pre-Application Files**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the clinical research interest of the site, and the work to be conducted as a member of the

consortium. 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.

- **Tab 6 – Submit Pre-Application**

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

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant’s organization’s Entity registration in the System for Award Management (SAM) well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

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

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline.*

The Grants.gov application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

Grants.gov application package components: For the Clinical Consortium Research Site 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. **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. Attachments Form

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (20-page limit): Upload as “ProjectNarrative.pdf.”** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

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, a description of the performance during 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 participate in collaborative clinical trials and function in the Consortium.
- Describe specific areas of clinical research interest, such as (but not limited to) novel drugs, combinatorial therapy schedules, surgical interventions, imaging techniques, and immunotherapies. Include overall scope of the clinical research 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 for any publications not publicly available in Attachment 2.

- Describe current procedures for and experience in ensuring compliance with FDA requirements for investigational agents.

(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.

(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 (including the development of new agents could lead to 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 in accordance with institutional policies.
 - Provide evidence of institutional commitment to providing facilities and resources in the conduct of Consortium operations.
- **Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named “Support.pdf.”** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in 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 Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may 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 support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- 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
 - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
 - Clearly identify all such property;
 - Identify the cost to the Federal government for use or license of such property, if applicable; or
 - Provide a statement that no property meeting this definition will be used on this project.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort,

when it can be anticipated, and the potential commercial use for the technology being developed.

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Describe the specific participation in the Consortium including the following elements:

- **Expertise:** Briefly describe the expertise of the research team behind the proposed effort.
 - **Resources:** Briefly describe access to resources. Provide evidence that supports the feasibility of participating in the Consortium.
 - **Prostate Cancer Population:** Briefly describe which prostate cancer population will be targeted for Consortium-led trials.
 - **Study Design:** Briefly describe the types of clinical trials to be proposed for conduct by the Consortium.
 - **Clinical Impact:** Briefly describe how participation in the Consortium may lead to a major impact on prostate cancer clinical management.
- **Attachment 4: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Clinical Consortium Research Site Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

- **Attachment 5: Impact Statement**

Describe how the PI and other personnel will contribute to the productive operations of the Consortium and aid in the movement of 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, and at least one of the PCRP focus areas.
- **Attachment 6: 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).

- **Attachment 7: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C.4., for detailed information.

- **PI Biographical Sketch (six-page limit):** Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (six-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.4., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

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

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

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 7, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. *If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. 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 either of these deadlines will result in submission rejection.

F. Other Submission Requirements

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

All extramural applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and PCRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in .*** Additional information about the two-tier 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 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 Process

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored 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.
- To what degree the intellectual and material property plan is appropriate, and demonstrates the institution's 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 for recruitment to Consortium-led trials.
- 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 direct maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement/Funding Opportunity.
 - 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 influence the review.

2. Programmatic Review: To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- a. **Ratings and evaluations of the peer reviewers**
- b. **Relevance to the mission of the DHP and FY16 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 email notification of posting of the funding recommendation in eBRAP. 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 specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

C. Withdrawal

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

- An FY16 PCRP Programmatic Panel 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 documentation. *A list of the FY16 PCRP Programmatic Panel members can be found at <http://cdmrp.army.mil/pcrp/panels/panel16>.*
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the

identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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.
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization 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, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

D. Reporting

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

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.

E. Award Transfers

Institution changes will not be allowed for the Clinical Consortium Research Site 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. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

F. 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. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version.

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210j]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. 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 eBRAP 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@eBRAP.org

C. Grants.gov Contact Center

Questions related to application submission through 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; International 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov 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	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Statement of Work: Upload as Attachment 4 with file name "SOW.pdf."	
	5	Impact Statement: Upload as Attachment 5 with file name "Impact.pdf."	
	6	Data- and Research Resource-Sharing Plan: Upload as Attachment 6 with file name "Sharing.pdf."	
	7	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 7 with file name "MFBudget.pdf," if applicable.	
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_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.	