

Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Prostate Cancer Biospecimen Resource Site Award

Funding Opportunity Number: W81XWH-14-PCRP-PCBRSA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 23, 2014
- **Invitation to Submit an Application:** late August 2014
- **Application Submission Deadline:** 11:59 p.m. ET, October 29, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, November 3, 2014
- **Peer Review:** December 2014
- **Programmatic Review:** February 2015

Change for Fiscal Year 2014: The CDMRP eReceipt System has been replaced with the Electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

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 2014 (FY14) 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 FY13 totaled \$1.29 billion. The FY14 appropriation is \$80 million (M).

The mission of the FY14 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 FY14*)

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](#)) applications to address one of the following four PCRP overarching challenges:

- Develop better tools for early detection of clinically relevant disease
- 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
- Develop strategies to optimize the physical and mental health of men with prostate cancer

PCRP Focus Areas

All applications for the FY14 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 Prostate Cancer Biospecimen Resource Site (PCBRSA) Award mechanism is being offered for the first time in FY14. This award mechanism is designed as an opportunity to expand upon the Prostate Cancer Pathology Resource Network Award, offered in FY09 and FY13.

Background: The FY13 PCRP Prostate Cancer Pathology Resource Network Award is currently supporting four organizations that together form the Prostate Cancer Biorepository Network (PCBN) (<http://www.prostatebiorepository.org/>). These organizations include Johns Hopkins University, designated as both the Coordinating Center and a Resource Site, and New York University, University of Washington, and Memorial Sloan-Kettering Cancer Center as three additional Resource Sites. The PCRP provides infrastructure support to these awardees for the development and maintenance of a prostate cancer biorepository that will facilitate the collection, processing, annotation, storage, and distribution of high-quality human prostate cancer biospecimens to be distributed to the prostate cancer research community. Biospecimens, which include tissues, blood, urine, prostatic fluids, and other source genomic and proteomic material, are collected from the broad spectrum of prostate cancer clinical stages, but major emphasis is placed on the acquisition and distribution of specimens in limited supply (e.g., castration-resistant disease, metastatic disease, tumors of the neuroendocrine phenotype, disproportionately affected populations, active surveillance populations, longitudinal specimens). The PCBN is also responsible for the collection, storage, and management of data derived from distributed biospecimens. All PCBN organizations are jointly responsible for maintaining and enhancing the activities of the biorepository.

The PCBN Coordinating Center, in addition to functioning as a Resource Site, serves as the nexus for information and planning, providing administrative, operational, and data management, and providing support to Resource Sites in implementing PCBN policies and standard operating procedures (SOPs). Additional responsibilities of the PCBN Coordinating Center are described in the FY13 Prostate Cancer Pathology Resource Network Award Program Announcement found at http://cdmrp.army.mil/funding/pa/13pcrppcprna_pa.pdf.

FY14 Funding Opportunity: The intent of the PCBRSA is to expand the PCBN by adding Resource Sites that will enhance the biorepository's utility to prostate cancer researchers through the provision of biospecimens that are **unique and/or in limited supply**. Both U.S. and international organizations are encouraged to apply to this Program Announcement/Funding Opportunity.

Biospecimens encouraged for the current funding opportunity include, but are not limited to:

- Samples from disproportionately affected populations
- Biopsies of metastatic lesions (particularly those with matched primary tissue)
- Pre- and post-neoadjuvant matched tissue samples and/or matched serum/plasma samples
- Serial samples of tissue or body fluids (e.g., serum, plasma, urine) that may include:
 - pre- and post-androgen deprivation therapy or metastatic therapy
 - pre- and post-castrate resistant status
 - high-risk prostate cancer (pT3 or prostatectomy Gleason score $\geq 4+3$), both pre-prostatectomy and at long-term (3+ years recurrence-free or time of recurrence or metastasis)
 - active surveillance baseline and at time of histopathologic progression (i.e., biopsy Gleason upgrading or increase in biopsy tumor volume)

Principal Investigators applying to this award mechanism are also encouraged to review the current specimens offered by the PCBN described at <http://www.prostatebiorepository.org/specimens>).

Applications for the PCBRSA should describe how the organization's contributions to the PCBN will enhance its ability to enable the prostate cancer research community to address the PCRP overarching challenges and PCRP focus areas.

The principal areas of responsibility for each Resource Site are as follows:

- 1. Biospecimens:** The biorepository collects, processes, annotates, stores, and distributes high-quality human prostate cancer biospecimens. Prospective collection of high-quality prostate cancer biospecimens is required of each Resource Site; however, the inclusion of previously collected high-quality biospecimens for distribution is encouraged. ***Resource Sites must ensure Institutional Review Board (IRB) approval and informed consent to share samples and data.*** In addition, each Resource Site should possess the ability to derivatize DNA, RNA, and proteins and utilize both standard and state-of-the-art technologies (e.g., laser capture microdissection, tissue microarrays) to provide the necessary biospecimen processing for a large range of prostate cancer research studies. Applications should include descriptions of how the quality of biospecimens collected and distributed will be assured. The Coordinating Center is responsible for developing and maintaining SOPs for biospecimen collection methods and post-collection processing for PCBN members and ultimately for sharing the SOPs with the wider prostate cancer research community.

- 2. Clinical Annotation of Biospecimens and Data Quality Assurance:** In addition to the importance of high-quality tissue specimens, annotation of the specimens is critical to the success of research studies to be conducted with samples obtained from the biorepository. Resource Sites must, to every extent possible, adhere to the common data elements (CDEs), standardized tissue annotation language, and quality assurance measures for clinical and pathological data and data transmission jointly established by the PCBN members. The extent of the clinical and pathologic annotation should include, at a minimum, (1) basic demographics (e.g., age, race); (2) clinical characterization (e.g., history of prior cancer, clinical stage, prostate specific antigen (PSA) levels, date or year of diagnosis, type and date of any treatment, recurrence/metastasis/death outcomes and time to event data); pathology data (e.g., biopsy primary and secondary Gleason grade, surgical pathology); and processing data (e.g., methods of collection, storage conditions). *Each Resource Site must ensure the active participation of an experienced uropathologist.*
- 3. Information and Data Management:** The PCBN maintains a comprehensive data management plan that includes a common informatics system to manage the biorepository resources and provide for ongoing data transfer, security, and integrity. All Resource Sites are expected to fully participate in and contribute to the data management plan, which will require:

 - the ability to share data in a flexible format and
 - the participation of personnel knowledgeable in informatics and/or database development.

Costs associated with developing and/or participating in the common informatics system are allowable and should be included in the proposed budget.
- 4. Intellectual and Material Transfer Agreements:** Since the biospecimen repository is a collaborative network between institutions, Resource Sites will work together with the Coordinating Center to resolve potential intellectual and material property issues and remove institutional barriers that might interfere with achieving the high levels of cooperation necessary for the success of the biorepository. Applications for the PCBRSA must provide documented evidence of institutional commitment to allowing specimens collected at Resource Sites to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.
- 5. Organizational Structure:** Overall direction and governance of the PCBN is provided by the Steering Committee, which is composed of the Coordinating Center PI (Chair), the Resource Site PIs and/or co-PIs, the Coordinating Center key personnel (i.e., Network Manager, Data Management Specialist, Data Quality Control Specialist), at least one prostate cancer survivor, and other personnel with key expertise. This committee is also responsible for establishing policies that govern SOPs (in accordance with NCI “Best Practices for Biospecimen Resources” (http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf) to include SOPs for quality control, specimen collection, processing, annotation, distribution, legal and ethical regulatory issues, policies for prioritization of specimen distribution, and fees and other costs to investigators for processing, handling, and shipping requests for samples. The Steering Committee coordinates the development of additional committees as necessary.

To ensure optimal conduct and oversight of activities, the PCBN convenes an External Advisory Board (EAB) twice yearly. All Resource Site PIs are required to participate in every EAB meeting.

Each Resource Site application must name a **Resource Site Coordinator**, who will work with the Coordinating Center Network Manager on Network-wide functions in addition to Site-specific functions. Overall, the Coordinating Center is responsible for the establishment and management of a communications plan and an ongoing communications system to maintain optimal operation of all Network components.

- 6. Performance Metrics:** Each PCBRSA recipient will be accountable to the following performance metrics, which if not met may result in funding restrictions:
- Contribution of biospecimens from a minimum of 50 patients per year, focusing on samples in limited supply and including appropriate clinical and pathology data
 - Documentation of specimen and data quality control
 - Harmonization of SOPs with existing PCBN SOPs
 - Successful data transfer to the PCBN Coordinating Center
 - Submission of reports in a timely manner

The Congressionally Directed Medical Research Programs (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 L.

C. Eligibility Information

To be eligible for this award, the PI must be:

- An independent investigator at or above the level of Assistant Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. 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 PCRPR PCPRNA, the predecessor of the PCBRSA award mechanism, was competed in FY13 and a network of four institutions was selected for award. Through those awards, the PCBN will be supported for 3 years, pending satisfactory performance. With this FY14 funding opportunity, one to two Resource Sites will be added to the PCBN. To align periods of award performance for the existing and new Network awardees, this current funding opportunity will

offer two years of funding. Should these two awards be offered again in future PCRFP funding opportunities, all FY13 and FY14 awardees for both mechanisms will be allowed to re-compete in the same funding year.

- The expected period of performance is **2** years.
- The maximum allowable direct costs for the entire period of performance are **\$400,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.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.***

For this award mechanism, direct costs:

Must be requested for:

- Travel for the PI to attend PCBN EAB meetings, to be held twice per year. Costs associated with travel to this meeting, up to \$3,600 per year, should be included in each year of the budget.
- Travel for the PI 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, should be included in Year 1 of the budget.

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

May be requested for (not all-inclusive):

- Salary
- Costs associated with planning and developing Network collaborations and resources
- Costs for derivatizing or other handling of biospecimens
- Costs for biospecimen procurement and storage
- Software licenses or other costs related to participation in biorepository information management
- Advertising/marketing costs
- Travel between Network organizations

- Travel costs of up to \$1,800 per year to attend scientific/technical meetings in addition to the required meetings described above. ***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.***

Intramural (DoD), other federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. 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. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from federal agencies submit applications, they must submit through Grants.gov. Therefore, 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.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other federal agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4. Research & Related Budget, for additional information on budget considerations for applications involving federal agencies.

The CDMRP expects to allot approximately \$0.6M to 1.3M of the \$80M FY14 PCRFP appropriation to fund approximately 1 or 2 Prostate Cancer Biospecimen Resource 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 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/>).

New for FY14: *The CDMRP has replaced its eReceipt System with eBRAP.* Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see *eBRAP User Guide* at <https://ebrap.org/eBRAP/public/UserGuide.pdf>). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***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. Any other application component cannot be changed after the end of the application verification period.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see [Section IV.A., Rejection](#)).

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-14-PCRP-PCBRSA.

B. Pre-Application Submission and Content Form

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or objectives after the pre-application is submitted.

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.

A change in organization after submission of the pre-application will not be allowed. Any other changes after the submission of the pre-application will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer. Contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 for assistance.

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):

- **Application Information – Tab 1**

- **Application Contacts – Tab 2**

- It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14 PCRP Integration Panel (IP) members should not be involved in any preapplication or application. A list of FY14 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel14>. 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@eBRAP.org or 301-682-5507.

- **Required Files – Tab 4**

Notes: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

Preproposal Narrative (two-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the potential Resource Site. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

Describe the proposed Resource Site using the outline below:

- **Multi-Institutional Collaboration and Biorepository Development:** Describe previous experience and accomplishments in multi-institutional collaboration and biorepository activities. Reference relevant publications.
- **Institutional Resources:** Describe the institutional resources, including the facilities; procurement, management, and distribution capabilities for high-quality biospecimens; data sharing capabilities, and other potentially unique strengths (e.g., patient populations, biospecimens in limited supply) of the applicant institution that support its ability to be a vital member of the PCBN. Describe the institutional commitment to allowing specimens collected at the proposed Resource Site to be sent to investigators at non-Network institutions.
- **Personnel:** Name and describe the PI and Key Personnel (e.g., uropathologist(s), other clinicians, scientists, Resource Site Coordinator, informatics expert, and patient advocates, as applicable) to be involved in the proposed Resource Site and their expected roles as they relate to the collection, processing, annotation, storage, and distribution of human prostate biospecimens.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application *must be uploaded as individual documents* and are limited to:

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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). Upload as “References.pdf.”
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative. Upload as “Abbreviations.pdf.”
- PI and Key Personnel Biographical Sketches (four-page limit per individual). Upload as “Biosketches.pdf.”

- **Submit Pre-Application – Tab 5**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the PCRIP, pre-applications will be screened by the PCRIP IP based on the following criteria:

- **Intent of the Award Mechanism:** To what degree the proposed Resource Site demonstrates the potential to enhance the biorepository’s utility to prostate cancer researchers through the provision of biospecimens that are unique and/or in limited supply.
- **Resource Site Team:** The extent to which the PI and Key Personnel possess the experience and expertise to successfully participate in and contribute to a multi-institutional biorepository.
- **Impact:** The extent to which the proposed Resource Site will, if successful, make a major impact on the field of prostate cancer research and enable investigators to conduct meaningful studies addressing the PCRIP overarching challenges and PCRIP focus areas.

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

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

C. Application Submission Content and Forms

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

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

New for FY14: *Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification.* The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: *Changes to either the Project Narrative or Budget are not allowed in eBRAP;* if such changes are required, the entire application package must be submitted through Grants.gov as a “Changed/Corrected Application” with the Previous Grants.gov Tracking ID *prior to the application submission deadline (which occurs earlier than the end of the application verification period).*

Grants.gov application package components: For the Prostate Cancer Biospecimen Resource 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. **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 (10-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 will result in administrative withdrawal of the application.

Describe the proposed Resource Site project in detail using the outline below:

(1) Experience and Expertise in Multi-Institutional Collaboration and Biorepository Development

- Describe previous experience and accomplishments in multi-institutional collaboration.
- Describe expertise, experience, and accomplishments related to the development, administration, and fiscal management of a biorepository.

- Describe previous experience with establishing and/or participating in communications systems and data management resources for multi-institutional projects.
- Reference relevant publications.

(2) Institutional Resources and Capabilities

Describe the institutional resources and capabilities, including the following aspects:

- The unique capabilities and strengths of the applicant institution to serve as a member of the PCBN, including evidence of knowledge and experience in store and tracking specimens and maintaining the integrity of the specimens.
- Evidence of institutional support, resources, and facilities to support biorepository activities in the context of a cooperative network of organizations.
- Evidence of institutional commitment to allow specimens collected at the Resource Site to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.
- Plans for resolving intellectual and material property issues between the Resource Site and other members of the PCBN.
- Access to patient populations: Describe the available patient populations. Provide documentation of access to the populations (and families, where appropriate) and ability to recruit patients and/or patient specimens identified as being in limited supply.

(3) Operational Management

Describe the plans for operational management, including the following:

- Plans for administration and day-to-day management of Resource Site operations.
- Plans for development and use of protocols, equipment, and training of personnel.
- Management and monitoring of biospecimen processing, annotation, storage, and distribution.
- Evidence of the expertise of all key personnel that will be involved in the Resource Site. Describe their expected roles as they relate to the collection, processing, annotation, storage, and distribution of human prostate biospecimens. Key personnel must include a **named Resource Site Coordinator** to expedite protocols through regulatory approval processes, expedite review, evaluation, selection, and prioritization of specimen distribution, develop protocols, coordinate personnel training, and coordinate patient participation and other biorepository activities across all institutions. Personnel must also include one or more experienced uropathologists and a person knowledgeable in informatics and/or database development.

(4) Biospecimen Management, Quality Assurance, and Distribution

Describe the plans for biospecimen management, quality assurance, and distribution, including the following key features and with consideration of the NCI's "Best Practices for Biospecimen Resources," as applicable:

- The model to be used for biospecimen collection, annotation, processing, storage, security, transport, and distribution; include how common data elements will be synchronized with those of the PCBN.
- Plans for the development and management of procedures for biospecimen inventory control, quality assurance, and quality control measures, including:
 - Registration, tracking, and reporting of patient participation and biospecimens;
 - Timely review and assessment of deposited biospecimen, clinical, and research data for consistency and accuracy; and
 - Development, implementation, and periodic evaluation of quality assurance and control procedures.
- Plans for contribution of biospecimens from at least the minimum number of 50 patients per year (to include patients from disproportionately affected populations).
- Plans for quality assurance, quality control, and monitoring of biospecimens to avoid sample variability, ensure specimen integrity (e.g., RNA, DNA, protein), and maximize efficiency.
- Plans for collecting and ensuring the quality of pathological and clinical biospecimen data and research data analyses.
- Evidence of IRB approval and informed consent to share samples and data.
- Oversight of privacy and confidentiality of patient data.

(5) Informatics and Data Management

Describe the plans for informatics and data management, including the following key features and with consideration of the NCI's "Best Practices for Biospecimen Resources," as applicable:

- Provide evidence of adequate resources for ongoing data transfer, including the ability to share data in a flexible format, and expertise for data management and maintenance of data security/confidentiality.
 - Describe the information technologies that will be used to facilitate routine communication and information and data sharing with the Coordinating Center and other Resource Sites.
- **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 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): 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 to be used for the efforts of the Prostate Cancer Pathology Resource Site. Letters should detail the willingness and capability of each institution to (1) provide the necessary facilities and resources for the biorepository activities; and (2) commitment to allow specimens collected at the Resource Site to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.
- Letters of Collaboration: 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.
 - Availability of and access to high-quality specimens, data sets or databases that are necessary for the success of the project.
 - Availability of and access to appropriate prostate cancer patient populations and/or families.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”

The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers typically rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

 - **Expertise:** Summarize the PI’s and Key Personnel’s commitment to and expertise in prostate cancer research and biorepository participation.

- ***Institutional Resources and Capabilities:*** Summarize the unique capabilities and strengths of the Resource Site. Include available resources, facilities, and prior experience in multi-institutional collaborations.
 - ***Biospecimen Management and Quality Assurance, Control, and Distribution:*** Summarize the model to be used for biospecimen collection, processing, annotation, and storage. State concisely how quality assurance and quality control will be managed to ensure specimen integrity and avoid sample variability.
 - ***Informatics and Data Management:*** Summarize the plan for data management, including provisions for ongoing data transfer, security, and integrity.
 - ***Prostate Cancer Populations:*** Describe the accessible prostate cancer populations that will be recruited for biospecimen acquisition and/or the accessible patient specimens. Include a description of any disproportionately affected populations to be included.
 - ***Impact:*** Describe how the proposed Network will have a significant impact on prostate cancer and/or prostate cancer research.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”

Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** 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 objective and rationale for the proposed effort in a manner that will be ***readily understood by readers without a background in science or medicine.***
 - Describe the ultimate applicability of the effort.
 - What types of patients will it help, and how will it help them?
 - What are the potential research applications, benefits, and risks?
 - What is the projected time it may take to achieve a patient-related outcome?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Prostate Cancer Biospecimen Resource 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.

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

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

- **Describe the short-term impact:** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the Resource Site’s contributions to the biorepository.
- **Describe the long-term impact:** Explain the anticipated long-term gains from the proposed efforts, including the anticipated advantages that the Resource Site’s participation in the biorepository may contribute to the goal of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.
- **PCRP Overarching Challenges and Focus Areas:** Describe how the proposed Resource Site will facilitate research that addresses one or more of the PCRP overarching challenges and one or more of the PCRP focus areas.

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

D. Verification of Grants.gov Application in eBRAP

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

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 application rejection.

F. 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 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, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is 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, U.S. Army Medical Research and Materiel Command (USAMRMC), based on (a) technical merit and (b) the relevance to the mission of the DHP and PCRP and to the specific intent of the award mechanism. The highestscoring applications from the first tier of review are not automatically recommended for funding. 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 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 Process

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Institutional Resources and Commitment**

- The extent to which there is evidence of strong commitment from the proposed Resource Site to provide the necessary resources and facilities for participation in the biospecimen repository, including operating in the context of a cooperative network, and allowing biospecimens to be shared with investigators outside the Network.
- The extent to which the proposed Resource Site has demonstrated the ability to provide unique resources that will complement and benefit the biorepository as a whole.
- The extent to which the proposed Resource Site has a demonstrated track record of procuring and sharing biospecimens and/or suitable plans to do so.
- How well the willingness and abilities of the proposed Resource Site to resolve intellectual and material property issues among participating institutions have been demonstrated.

- **Personnel**

- How well the Resource Site PI and other key personnel have demonstrated the expertise, experience, and accomplishments to enable robust participation in a prostate cancer biorepository.
- How well the Resource Site PI and other key personnel have demonstrated previous success in multi-institutional collaborations.
- Whether the required personnel (experienced uropathologist, Resource Site Coordinator, and informatics/database expert) are included.
- Whether there are sufficient levels of effort for the successful conduct of the proposed work.

- **Biospecimen Procurement and Management**

- How well the capability to synchronize CDEs with the PCBN have been demonstrated.
- The extent to which the plans for the development and management of procedures for biospecimen inventory control, quality assurance, and quality control measures are appropriate.

- Whether the proposed Resource Site has a track record to support its ability to meet the performance metrics (e.g., specimens for a minimum of 50 patients per year).
- The extent to which the plans for biospecimen quality assurance and quality control are appropriate.
- **Operational and Data Management**
 - Whether the proposed plan for coordinated ongoing Resource Site communication with the existing Network are appropriately robust.
 - The extent to which the plans for sharing of data between the Pathology Resource Network and with the prostate cancer research community, including all data derived from internal and external studies of the biorepository specimens, are sufficient.
 - Whether there are adequate plans to harmonize the Resource Site's informatics system with that of the existing Network.
 - Whether the proposed plan for data management will provide appropriate access to data, data security and confidentiality, and data integrity.
 - Whether the proposed data management plan is appropriate with respect to quality control and quality assurance.
 - The degree to which the informatics support will facilitate data sharing with the Network as a whole.
- **Regulatory Issues**
 - Whether there are appropriate plans for addressing regulatory issues associated with the protection of human subjects and the use of human biospecimens in research.
 - Whether all relevant privacy issues have been addressed appropriately.
 - Whether the plans for data acquisition and storage will sufficiently maintain patient confidentiality.
 - Whether the plans for ensuring IRB approval and informed consent are sufficiently developed.
- **Participant Access and Recruitment**
 - The degree to which the PI has demonstrated enhanced access to patient specimens that are in limited supply for prostate cancer research.
 - Whether there is sufficient evidence of access to and ability to recruit patients from disproportionately affected populations.
 - How well the PI has demonstrated superior capabilities in obtaining high-quality biospecimens.

- **Impact**

- The extent to which the Resource Site’s contributions to the biorepository as proposed will, if successful, make a major impact on the field of prostate cancer research and enable investigators to conduct meaningful studies addressing the PCRP overarching challenges and PCRP focus areas.

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 effort 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, 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 FY14 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
- 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 pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

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

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY14 PCRP 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 documentation. A list of the FY14 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panels14>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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.
- The invited application does not propose the same effort described in the pre-application.

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, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

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

At the Government's discretion, each participant Site may be expected to participate in a site visit by the Government or its designee.

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

E. Award Transfers

The transfer of a Prostate Cancer Biospecimen Resource Site Award to another institution is not allowed.

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

F. Pre-Award Meeting

At the Government's discretion, the PI and Resource Site 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 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

B. 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

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 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

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
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.	