

# **Program Announcement**

**for the**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Prostate Cancer Research Program**

### **Prostate Cancer Pathology Resource Network Award**

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

**Catalog of Federal Domestic Assistance Number: 12.420**

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 18, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 9, 2013
- **Peer Review:** December 2013
- **Programmatic Review** March 2014

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

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

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

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

### PCRP Overarching Challenges

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

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

### PCRP Focus Areas (revised for FY13)

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

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

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

## **B. Award Information**

The Prostate Cancer Pathology Resource Network (PCPRN or Network) Award mechanism was previously offered in FY09. At that time, five PCPRN Award applications were received for the Coordinating Center plus Pathology Resource Site, with one being funded, and nine were received for Pathology Resource Sites, with one being funded. ***NEW for FY13: Applications will now be submitted by Coordinating Centers in collaboration with their chosen Pathology Resource Sites.***

The PCRP PCPRN Award is intended to provide infrastructure support for the development and maintenance of a prostate cancer biorepository through a collaborative network across multiple institutions that will facilitate the collection, processing, annotation, storage, and distribution of high-quality human prostate cancer biospecimens. Biospecimens may be collected from the broad spectrum of prostate cancer clinical stages, but major emphasis must be 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 Network must also collect, store, and manage data derived from the distributed biospecimens, including images of the hematoxylin and eosin (H & E) stained samples.

Applications should describe how the development of the Network biorepository will enable the prostate cancer research community to address the PCRP overarching challenges and PCRP focus areas by utilizing Network biospecimens. Applications should propose a clearly defined mission that will guide the proposed Network's biospecimen collection, distribution, and data collection processes. In addition, institutions must demonstrate a commitment and plan to secure additional funds from other sources to continue operations of the Network after the end of the PCRP award performance period.

***The Network will consist of four Pathology Resource Sites and a Coordinating Center, which will also be the location of one of the Pathology Resource Sites. These organizations will be jointly responsible for developing and maintaining the biorepository for prostate cancer research.*** The Coordinating Center and Pathology Resource Sites should together design the proposed biorepository. It is expected that the Coordinating Center will provide unique resources that may not be available at the Pathology Resource Sites and can be leveraged for the biorepository as a whole. Additionally, Pathology Resource Sites should each 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. Both U.S. and international organizations should be considered for inclusion in applications for this award. ***The Pathology Resource Sites should be selected for the individual contributions each can make to the biorepository; the contributions need not be equal but rather of unique value to the biorepository as a whole. If the contributions vary significantly between Pathology Resource Sites, variance in the budgets allocated to sites should be well described in the budget justification.***

The Prostate Cancer Pathology Resource Network Coordinating Center, in addition to functioning as a Pathology Resource Site, will serve as the nexus for Network information and planning, providing administrative, operational, and data management, and providing support to Pathology Resource Sites in implementing Network policies and standard operating procedures (SOPs). Therefore, the Coordinating Center will have multidisciplinary expertise and extensive experience in multi-institutional collaborations in prostate cancer research. Applications from organizations with resources (such as sufficient equipment for biorepository functions, pathology and histochemistry infrastructure, informatics and information infrastructure to support connectivity between the Coordinating Center and Pathology Resource Sites for data transfer) already in place to support the development of a biorepository are encouraged. Principal Investigators (PIs) are expected to have experience and expertise in human biospecimen procurement, annotation, storage, and distribution, and in developing and operating a biospecimen repository. PIs should have a proven track record in human pathology.

***Multiple PI Option:*** Due to the multi-institutional nature of the PCPRN Award mechanism, if the Coordinating Center does not wish to apply for a single award with multiple subawards, the Multiple PI Option is available to accommodate ***up to four*** PIs, each of whom will receive a separate award. Whether any of the required Pathology Resource Sites other than the Site located at the Coordinating Center will submit a separate application using this option, rather than as a subcomponent of the Coordinating Center application, is at the discretion of the applicants. Coordinating Center PIs should consider that submission of applications using the Multiple PI Option will (1) reduce the amount of Coordinating Center direct costs that must be used to support Pathology Resource Site indirect costs, (2) increase Government oversight of each Pathology Resource Site, and (3) reduce flexibility should any Pathology Resource Site not perform as expected. All applications for a single proposed biorepository will be associated with each other through the CDMRP eReceipt System. In using the Multiple PI Option, the Coordinating Center PI will be the Initiating PI. Pathology Resource Site PIs will be the Partnering PIs at organizations other than that of the Coordinating Center. The Initiating and Partnering PIs have different application submission requirements; however, each PI should contribute to the preparation of each of the application components.

The Network Award recipient(s) are encouraged to conduct a workshop to convene Network PIs, other biorepository participants, and other experts in the field of biospecimen science during the period of performance for the award. If a plan to conduct a workshop is included in the application, a description should be provided that details how the proposed workshop would enhance the usefulness of the biorepository in facilitating meaningful and innovative prostate cancer research. While the conduct of this workshop is not mandatory, appropriate costs should be accounted for in the proposed budget if a workshop effort is included in the application.

*The principal areas of responsibility for the Prostate Cancer Pathology Resource Network are as follows:*

- 1. Biospecimens:** The biorepository will collect, process, annotate, store, and distribute high-quality human prostate cancer biospecimens and matched or unmatched normal tissues and other non-anatomic pathologic samples to include blood, urine, prostatic fluids, and other source genomic and proteomic material. *Prospective collection of high-quality prostate cancer biospecimens is required; however, the inclusion of previously collected high-quality biospecimens for distribution by the biorepository is encouraged.* Applications should include descriptions of how the quality of biospecimens collected and distributed will be assured. Information regarding the methods of collection, such as precise surgical excision procedures and post-operative specimen manipulation, phlebotomy, fine needle aspiration, and others, should be part of the data collected on all specimens. The Coordinating Center will be responsible for developing and maintaining SOPs for biospecimen collection methods and post-collection processing for Network members and ultimately for sharing with the wider prostate cancer research community.

*The Network must focus significant attention on the collection and distribution of biospecimens currently in limited supply for research (e.g., castration-resistant disease, metastatic disease, tumors of the neuroendocrine phenotype, disproportionately affected populations, active surveillance populations, longitudinal specimens), that will foster critical investigations in prostate cancer and accelerate advancement toward the PCRP mission of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.*

Successful plans for biospecimen collection may also include multiple tumor foci (of studies that address tumor heterogeneity) and multiple sites of metastasis. Applications should include justification for the types of biospecimens proposed for collection, whether by using data from surveys of the prostate cancer research community or by other means. Applications should also include plans for ongoing monitoring of research needs to best facilitate utilization of the resource.

- 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. Within the framework of the data management plan, the Network must establish and maintain common data elements (CDEs) and standardized language to annotate tissue specimens collected for the biorepository. The extent of the clinical annotation should include data on (1) patient history and demography, (2) characterization of individual pathological cases to include grade, TNM staging, zonal origin of tumor, biospecimen size, storage conditions, the existence of case-matched normal biospecimens, and other standard parameters, (3) patient treatment to include adjuvant or neoadjuvant therapeutic interventions, including attention to interventions resulting from participation in clinical trials, and (4) outcome such as disease progression, recurrence, and/or prostate specific antigen (PSA) levels or other biochemical status. *Given the importance of clinical annotation, the Prostate Cancer Pathology Resource Network must provide for regular updating of annotated data in the repository.* To ensure the quality of the biospecimens and the consistency and

accuracy of data in the repository, the Network is expected to develop quality assurance measures for clinical and pathological data and data transmission by establishing policies for appropriate quality control and quality assurance.

- 3. Informatics and Data Management:** It is expected that the Network will develop and maintain 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. The system should remain current and responsive to the prostate cancer research community so that data can be both retrieved and deposited into the system. The system may include, but is not limited to, ongoing processes to improve and update Network access to resources internal and external to the Network, and developing new informatics strategies to harmonize the biorepository informatics resources with the informatics of other similar efforts nationwide, such as the National Cancer Informatics Program (NCIP) (<http://cbit.nci.nih.gov/ncip>). *Costs associated with developing the common informatics system are allowable and, if necessary, should be included in the proposed budget.*

PIs must provide a plan to deposit all data generated from the use of biospecimens obtained from the funded biorepository into a common information grid. *Investigators utilizing the Network biospecimens must agree to share the resulting data after publication and as prescribed by the Network and in accordance with journal policies.* The data-sharing plan must include steps for sharing the data with the prostate cancer research community through an internet-accessible source administered by the Coordinating Center. In addition, to maximize the impact of the biorepository, protocols and other methods used to derive tests, assays, and associated data from the biorepository specimens must be available to the entire prostate cancer research community via an open source system such as public websites.

- 4. Informed Consent:** Applications for the PCPRN Award are expected to demonstrate plans for establishing and managing procedures to ensure requests for use of biospecimens are in compliance with the local institutional review boards (IRBs) for the conduct of research and the protection of human subjects. Assurances should be made for appropriate acquisition of patient-informed consent, with tiers as appropriate, to include clinicians, surgeons, or other personnel necessary for the consent process, and disassociation of patient identities from biospecimens. PIs should also address how informed consent will be handled beyond consent obtained for surgical procedures. This includes specimens collected during routine medical care that will be used for future research purposes.
- 5. Intellectual Property and Material Transfer Agreements:** Since the biospecimen repository will be a collaborative network of institutions, the Network PIs 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 Network. Applications for the PCPRN Award must provide documented evidence of institutional commitment to allowing specimens collected at Pathology Resource Sites to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.

**6. Organizational Structure:** The overall organizational structure of the Prostate Cancer Pathology Resource Network is *four* procurement Pathology Resource Sites and one Coordinating Center. The Coordinating Center organization will serve as one of the four Pathology Resource Sites, in addition to serving as the nexus for Network information and planning, providing administrative, operational, and data management. The Coordinating Center PI will serve as the Director of the Network and the Chair of the Steering Committee. In addition to the Coordinating Center PI and the Pathology Resource Site PIs and collaborators, other key personnel in the Network include a:

- Coordinating Center **Network Manager** who will assist with daily operations of the Coordinating Center;
- Coordinating Center **Data Management Specialist** who will interact and oversee all informatics and data management within the Network;
- Coordinating Center **Data Quality Control Specialist** who will be responsible for implementing established operational procedures to ensure the quality of biospecimens and biospecimen data across the Network and the shared information grid; and
- **Pathology Resource Site Coordinator** (one for each Site) who will work with the Coordinating Center Network Manager on Network-wide functions in addition to Site-specific functions.

**Network Committees:** The Network will be required to have a committee structure that allows for an overall quality assurance plan with the responsibility of:

- Coordinating and developing protocols, equipment, and training of personnel;
- Coordinating regulatory issues including compliance of local IRB approvals;
- Coordinating oversight of privacy and confidentiality of patient data; and
- Managing biospecimen processing, annotation, storage, and distribution.

A **Steering Committee** composed of Coordinating Center PI (Chair), Pathology Resource Site PIs and/or co-PIs, Coordinating Center key personnel (Network Manager, Data Management Specialist, Data Quality Control Specialist), at least one *prostate cancer survivor* (Consumer Advocate), and other personnel with key expertise will assume the role of the governing body with responsibility for operation of the biorepository Network. This committee will also be 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](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 will coordinate the development of additional committees as necessary for development of common data elements, protocol coordination, regulatory coordination (IRB) and bioethics review, intellectual/material property coordination, data collection, data management (data quality, security, and compatibility), and prioritization and distribution of biospecimens. Representatives of the PCRP, Congressionally Directed

Medical Research Programs (CDMRP), and/or US Army Medical Research and Materiel Command (USAMRMC) must be invited to participate as members of the Steering Committee.

**External Advisory Board:** To ensure optimal conduct and oversight of Network activities, the Network will propose and develop an External Advisory Board (EAB). Applications must include a description of the proposed EAB members, the role of each member (e.g., scientific, business, or other type of review), evidence of agreement to serve, and plans for interaction between the EAB and Network members, which should, at a minimum, include meetings (whether in-person or by other means) no less than twice yearly. Support for this interaction must be included in the proposed budget. In selecting EAB advisors, the types of samples to be collected should be considered, as well as the importance of external expertise in pathology, biobanking, and current advancements in biospecimen science.

The Government reserves the right to require augmentation of the EAB membership prior to or during the award performance period. In addition, representatives of the PCRP, CDMRP, and/or USAMRMC must be invited to participate in meetings involving the EAB. The Government reserves the right to direct the location of any in-person meeting. Support for Government participation should not be included in the proposed budget.

**Consumer Advocate Participation:** The inclusion of one or more prostate cancer consumer advocates is required, as their participation should be an integral part of Network activities. These advocates must be individuals who have been diagnosed with prostate cancer and have a high level of familiarity with current issues in prostate cancer research. They will have an active role in ongoing Network oversight including discussion and decision making on participant recruitment, project evaluation, and dissemination of information to the prostate cancer research community and/or public. Examples of appropriate integration include membership on the Steering Committee and other Network committee(s) and attendance at Network-related meetings.

***Overall, the Coordinating Center will be responsible for the establishment and management of a communications plan and an ongoing communications system to maintain optimal operation of all Network components.***

- 7. Performance Metrics:** The PCPRN Award recipient(s) will be accountable to the following performance metrics, upon which continued funding will be contingent after the first 12 months of the award.
- The Coordinating Center must develop and meet a defined set of objectives or milestones as set forth in the Statement of Work.
  - The Network Coordinating Center, in collaboration with the Pathology Resource Sites, must develop SOPs for prospective biospecimen collection methods and post-collection processing. Following EAB review of the SOPs, the Coordinating Center must provide documentation of these SOPs to the Government no later than the end of the first year of performance.
  - The Network Coordinating Center must demonstrate substantive engagement with the prostate cancer research community, including but not limited to surveys on

biorepository specimen types needed and strategies to foster confidence and enhance utility of the biorepository, ongoing documentation of Letters of Intent for utilization of specimens, to include the number of requests received, approved, or rejected and the types and timeliness of specimens distributed. The Coordinating Center must demonstrate the impact of the biospecimens distributed by tracking of the number of publications involving the use of Network biospecimens.

- The Network Coordinating Center must demonstrate sufficient data quality control and assurance through documentation that standard operating procedures are being followed for biospecimen annotation (e.g., patient history and demographic, clinical history, treatment, pathology, and outcome such as disease progression, recurrence, and prostate specific antigen [PSA] levels and/or other biochemical status). This may include audits of unacceptable data (record, clinical, pathological) returned to Sites for review and correction for data quality assurance.
- The Network Coordinating Center must demonstrate sufficient and ongoing efforts to harmonize the biorepository informatics system with the informatics systems of other national biorepositories.
- Each Pathology Resource Site must contribute prospectively collected biospecimens from a minimum of 50 patients per year, focusing on samples in limited supply and documented to be the most needed by the prostate cancer research community, with the expectation that biospecimen contribution will exceed the minimum requirement. Biospecimens from disproportionately affected populations should match or exceed the existing disproportionately affected patient population available to the Pathology Resource Site. In addition to the primary goal of collecting tissue specimens, associated blood, urine, prostatic fluids, and other biological samples should also be collected.
- Each Pathology Resource Site must submit quality data and reports in a timely manner as outlined by the Coordinating Center. This includes, but is not limited to, requests for biospecimens, entry of data upon sample acquisition, and all subsequent information updates.

### **C. Eligibility Information**

To be eligible for this award, the PI at each Network institution must be:

- An independent investigator with access to appropriate facilities, and
- At or above the level of an Assistant Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## D. Funding

The PCRCP plans to invest \$4.8M in the Prostate Cancer Pathology Resource Award over a 3-year period. A total of \$1.6M will be allocated from the FY13 budget to fund the first year of performance. Options will be included for continued performance in subsequent years with \$1.6M expected from each of the FY14–FY15 budgets to fund the options. The initial performance period of the award and each option period will be for twelve months. ***Exercise of the options for continued performance is contingent on receipt of sufficient Congressional appropriations to the PCRCP in FY14–FY15 and acceptable performance by the recipient.***

- The expected period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$3M**. This amount may not be exceeded whether the PIs choose to submit a single application or multiple applications through the Multiple PI Option; the combined amount for all applications may not exceed **\$3M** in direct costs. Budget amounts for the Pathology Network Sites should reflect the resources to be contributed; however, if the budgets between Pathology Resource Sites differ significantly, the differences must be well justified in the budget justification.
- In addition to the direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

***Exercise of the options*** for continued performance for the Network after the first year will be contingent upon meeting the performance metrics and upon receipt of sufficient Congressional appropriations to the PCRCP in FY14 and FY15.

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

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for attendance at EAB review meetings (including costs for all appropriate personnel), to be held a minimum of two times per year. Costs should also be including for conducting these meetings.
- Travel for the Coordinating Center PI and the PI of each Pathology Resource Site to attend a 1-day meeting to be held in the National Capital Area during the award period of performance. This meeting will be held to provide a presentation on progress. Costs associated with travel to this meeting, up to \$1,800 per person, should be included in Year 2 of the budget. ***If the Multiple PI Option is employed, travel costs should be requested only for each of the PIs on their separate budgets.***

- Travel for the PI and the PI of each Pathology Resource Site to attend one DoD PCRP Innovative Minds in Prostate Cancer Today (IMPACT) meeting, which is held to disseminate the results of PCRP-sponsored research. Costs associated with travel to this meeting, up to \$1,800 per person, should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. ***If the Multiple PI Option is employed, travel costs should be requested only for each of the PIs on their separate budgets.***

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

May be requested for (not all-inclusive):

- Salary
- Development of software, databases, inventory systems, websites, and/or other information technology
- Purchase of equipment, including computers (equipment purchases should not exceed \$50,000 total)
- Advertising/marketing costs
- Other costs associated with planning and developing Network collaborations and resources
- Network meetings including travel among Network PIs and staff
- Travel to scientific meetings
- Planning and travel costs for Network symposia or workshops
- Travel costs of up to \$1,800 per year per person for five individuals among the PI(s) and the key personnel to attend scientific/technical meetings in addition to the required meeting described above. ***If the Multiple PI Option is employed, these costs can be requested on each of the PIs' separate budgets, with travel costs for one person per site allowed.***

***The CDMRP expects to allot approximately \$1.6M of the \$80M FY13 PCRP appropriation to fund approximately one PCNRNA, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program. Options will be included for continued performance in subsequent years with approximately \$1.6M expected from each of the FY14–FY15 budgets to fund the options.***

## **II. SUBMISSION INFORMATION**

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

**Multiple PI Option:** The PCPRN Award mechanism is structured to accommodate up to four PIs, each of whom will receive a separate award. Whether any of the required Pathology Resource Sites other than the Site located at the Coordinating Center will submit a separate application using this option, rather than as a subcomponent of the Coordinating Center application, is at the discretion of the applicants. Coordinating Center PIs should consider that submission of applications using the Multiple PI Option will (1) reduce the amount of Coordinating Center direct costs that must be used to support Pathology Resource Site indirect costs, (2) increase Government oversight of each Pathology Resource Site, and (3) reduce flexibility should any Pathology Resource Site not perform as expected. All applications for a single proposed biorepository will be associated with each other through the CDMRP eReceipt System. In using the Multiple PI Option, the Coordinating Center PI will be the Initiating PI. Pathology Resource Site PIs will be the Partnering PIs at organizations other than that of the Coordinating Center. Initiating and Partnering PIs each have different submission requirements; however, each PI should contribute significantly to the development of the proposed project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PIs. The Partnering PIs will then be notified separately by email. Please note that each Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.

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

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

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

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

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

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

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

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

FY13 PCRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP [Help Desk](#) (301-682-5507).

- **Required Files – Tab 4**

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

- **Submit Pre-Application – Tab 5**

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

- **Other Documents Tab**

No additional documents are required.

### C. Application Submission Content and Form

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

*Multiple PI Option: Initiating and Partnering PIs will each be assigned unique log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.*

#### Application Components for the PI or Initiating PI:

**Grants.gov application package components:** For the Prostate Cancer Pathology Resource Network 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 (40-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 project in detail using the outline below.

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

For both the Coordinating Center PI and the Pathology Network Site PIs:

- 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 communications systems and data management resources for multi-institutional projects.
- Reference relevant publications.

*If any of the institutions is a previous recipient of a PCRP Prostate Cancer Pathology Network Award, whether as Coordinating Center or Pathology Resource Site, a description of the performance of that award must be included.*

**(2) Organizational Structure**

For both the Coordinating Center and the Pathology Network Sites, describe the organizational structure, including the following key features and with consideration of the NCI's "Best Practices for Biospecimen Resources," as applicable:

- The structure of interaction amongst the Coordinating Center and Pathology Resource Sites (a chart format for this information is encouraged).
- Plans for administration and day-to-day management of Network operations.
- Communication and Network Interaction: Describe the communication plan between the Coordinating Center and Pathology Resource Sites. Plans should address the following: Methods for information distribution within the Network, information technologies that will be used to facilitate routine multi-institutional communication, and ongoing communication (including required Workshops) and data sharing.
- Standardized operations across institutions.
- Coordination and development of protocols, equipment, and training of personnel.
- Coordination of regulatory issues.
- Coordination and oversight of privacy and confidentiality of patient data.
- Procedures for ensuring that research projects with requests for use of biospecimens are in compliance with local IRB approvals for the conduct of research and the protection of human subjects.

- Management and monitoring of biospecimen processing, annotation, storage, and distribution.
- Procedures for developing SOPs for collection, processing, annotation using standardized language, storage, and distribution of prostate cancer and normal biospecimens including those from ethnically diverse and disproportionately affected populations.
- Network committees that will be responsible for approval of all standard operating procedures and laboratory protocols, and prioritization of biospecimen distribution to prostate cancer investigators to ensure appropriate and efficient distribution of samples and attention to studies that address PCRP focus areas.
- Involvement of a prostate cancer consumer advocate. Provide a named consumer advocate to serve as a member of the Steering Committee. Describe the consumer advocate's familiarity with current issues in prostate cancer and how he will play an active role in the Network, including oversight, participant recruitment, program evaluation, dissemination of information to prostate cancer communities and/or the public, and interactions with other participants to strengthen the overall Network.
- Oversight by an EAB for scientific review, data monitoring, and evaluation. Include a description of the proposed EAB members, the role of each member (e.g., scientific, business, or other type of review), evidence of agreement to serve, and plans for interaction between the EAB and Network members, which should, at a minimum, include meetings (whether in person or by other means) no less than twice yearly. Support for this interaction must be included in the proposed budget. In selecting EAB advisors, the types of samples to be collected should be considered, as well as the importance of external expertise in pathology, biobanking, and current advancements in biospecimen science.

### **(3) Institutional Resources**

For both the Coordinating Center and the Pathology Network Sites, describe the institutional resources, including the following aspects:

- The unique capabilities and strengths of the applicant institution to serve as a member of the Prostate Cancer Pathology Resource Network.
- Provide evidence of institutional support, resources, and facilities for the development of a biospecimen repository and its operation in the context of a cooperative network of organizations.
- Provide evidence of institutional commitment to allow specimens collected at Pathology Resource Sites to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.
- Provide a plan for resolving intellectual and material property issues among participating institutions, and how material transfer agreements (MTA) will be established.

- Describe the unique capabilities and strengths of the institutions selected to serve as Pathology Resource Site.
- Document access to patient populations: Describe the 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 and from ethnically diverse and disproportionately affected populations.

#### (4) Operational Management

For both the Coordinating Center and the Pathology Resource Sites, describe the plans for organizational management, including the following key features and with consideration of the NCI's "Best Practices for Biospecimen Resources," as applicable:

- Provide evidence of the expertise of all key personnel that will be involved in the Coordinating Center and the Pathology Resource Sites, respectively. 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 Network Manager** at the Coordinating Center who will interact with the four Sites to coordinate activities across all Sites, including interacting with a Pathology Resource Site Coordinator at each site 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.
- Include a **named Data Quality Control Specialist** at the Coordinating Center who will interact with all Pathology Resource Sites and oversee implementation of established operational procedures to ensure the quality of biospecimens and biospecimen data across the Network and shared information grid.
- Describe plans for collecting and ensuring the quality of pathological and clinical biospecimen data and research data analyses.
- Include a plan for sharing biospecimens across the Network.
- Include a plan for processing, evaluating, and prioritizing requests for biospecimens from Network members and other investigators, including potential restrictions governing use of biospecimens by commercial entities.
- Describe plans for harmonizing the Prostate Cancer Pathology Resource Network informatics system with other national biorepository informatics systems (e.g., NCIP).
- Outline a plan for ensuring rapid publication and other public dissemination of data generated by Network investigators, and procedures for timely release of data obtained from use of biospecimens following publication of significant findings by non-Network investigators.

- Provide a plan for the development and management of procedures for biospecimen inventory control, quality assurance, and quality control measures across institutions, including:
  - A plan for regular monitoring of biospecimen quality, biospecimen clinical and pathological data, and data transmission across the Network as described in the **Clinical Annotation of Biospecimens and Data Quality Assurance** section above;
  - Registration, tracking, and reporting of patient participation and biospecimens;
  - Timely review and assessment of biospecimen data, deposited clinical annotated data and deposited research data for consistency and accuracy; and,
  - Development, implementation, and periodic evaluation of quality assurance and control procedures.
- Development and implementation of comprehensive data collection and data management systems to manage biorepository resources and provide for ongoing needs of all Sites in terms of access to data, data transfer, data security, and data integrity.
- Development and implementation of procedures for the timely release of all data obtained from use of biospecimens following publication of significant findings.
- Plans for contribution by each Pathology Resource Site of biospecimens from at least the minimum number of 50 patients per year (to include patients from disproportionately affected populations).
- Development and implementation of procedures for the timely publication of research results.
- (Optional): Plans for a workshop to convene Network PIs, other biorepository participants, and other experts in the field of biospecimen science. The proposed workshop should enhance the usefulness of the biorepository in facilitating meaningful and innovative prostate cancer research.

**(5) Biospecimen Management, Quality Assurance, and Distribution**

For both the Coordinating Center and the Pathology Resource Sites, 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, and distribution; include how common data elements will be developed and methods/applications for data collection and transmission.
- Methods for biospecimen collection, tracking, storage, transport, distribution, and security.

- 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 biospecimen management, to include methods for biospecimen collection, tracking, storage, integrity, transport distribution, and security.
- Descriptions of quality control measures for biospecimens, data, and monitoring to avoid sample variability.
- Plans for collecting and ensuring the quality of pathological and clinical biospecimen data and research data analyses.

#### **(6) Informatics and Data Management**

For both the Coordinating Center and the Pathology Resource, 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:

- Include a **named Data Management Specialist** at the Coordinating Center who will interact with all Pathology Resource Site Coordinators to optimize informatics and data management within the Network.
- Describe the common informational system to be used in the Network: include database design, operation, and maintenance; inventory control system(s); access; and searchable functions for biospecimen information and research data.
- Describe the overall planned approach to data collection and management.
- Describe the plan for ongoing data transfer, security, and integrity.
- Describe the plan for managing the resources of the Network while remaining current and responsive to non-Network prostate cancer investigators.
- Include the plan for sharing all data derived from Network biorepository specimens, whether generated by Network or non-Network investigators.
- Provide evidence of adequate resources for ongoing data transfer, and expertise for data management and maintenance of data security/confidentiality.
- Describe procedures for managing the resources of the Pathology Resource Site while remaining current and responsive to non-Network prostate cancer investigators.
- Describe the information technologies that will be used to facilitate routine communication and information and data sharing with the Coordinating Center and other Pathology Network Sites.

#### **(7) Legal, Ethical, and Human Subject Issues**

For both the Coordinating Center and the Pathology Resource Sites, describe the plans to manage legal, ethical, and human subject issues, including the

following key features and with consideration of the NCI's "Best Practices for Biospecimen Resources," as applicable:

- Outline the ethical and legal procedures and policies that will be followed for collection and use of biospecimens in research.
- Include a description of the methods for obtaining informed, tiered patient consent, how patient identities will be disassociated from biospecimens provided to investigators, and how research results from the biospecimens will be made available to clinicians of patient participants.
- Describe the process through which all Sites in the Network will adhere to a common policy governing legal, ethical and human subject issues.
- Describe procedures for ensuring compliance with ethical and legal involvement of human subjects, and issues involved in the collection and use of biospecimens in research.

#### **(8) Financial Management and Marketing of Resource Specimens**

- Describe how the Network intends to secure funds from other sources to leverage Network resources to continue operation of the Pathology Resource Network beyond the performance period for the PCRP award.
- Include plans for advertising/marketing for both obtaining and distributing the biospecimens to the prostate cancer research community.
- **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 (ten-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 Network. Letters should detail the willingness and capability of each institution to (1) provide the necessary facilities and resources for the Network's administrative and biorepository activities; and (2) commitment to allow specimens collected at Pathology Resource Sites 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 Network PIs have the support or resources necessary for the proposed work:
  - Required (Coordinating Center only): Provide a signed letter from the named prostate cancer consumer advocate that describes his familiarity with current issues in prostate cancer research and how he will support the PIs and the project.
  - If applicable: Provide a signed letter from each collaborating individual or institution that will demonstrate that the PI has the resources necessary for the proposed project, including but not limited to:
    - 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 (two-page limit):** Upload as "TechAbs.pdf."

The technical abstract should be written using the outline below. Programmatic reviewers do not typically have access to the full application and therefore rely on the technical abstract for appropriate description of the project's key aspects. Clarity and completeness within the space limitation are highly important.

  - ***Expertise:*** Summarize the key personnel's (including the PIs, consumer advocate(s), and other key personnel) commitment to and expertise in prostate cancer research and pathology.
  - ***Coordinating Center Organizational Structure and Operational Management:*** Briefly outline the overall organizational structure, administration, and model for standard operating procedures.
  - ***Biospecimen Management and Quality Assurance, Control, and Distribution:*** Briefly describe the model to be used for biospecimen collection, processing, annotation, storage, and distribution. State concisely how quality assurance and quality control will be managed to ensure specimen integrity and avoid sample variability.

- ***Informatics and Data Management:*** Describe the plan for data management, including a common informational (informatics) system to manage the biorepository resources, provide for ongoing data transfer, security, and integrity. State briefly how this system will be used to facilitate communication and Network interactions between Network Sites, and the Coordinating Center.
- ***Institutional Resources:*** Summarize the unique capabilities and strengths of the institutions serving as Coordinating Center and Pathology Resource Sites. Include available resources, facilities, and prior experience in multi-institutional collaborations.
- ***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:** N/A

- Not required at this time. Leave Attachment 4 space blank.

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

***For applications including the Multiple PI Option, each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PIs should be noted for each task.*** An example of this type of SOW is available at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

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

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

- ***Describe the short-term impact:*** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the development of the biorepository.
- ***Describe the long-term impact:*** Explain the anticipated long-term gains from the proposed project, including the long-term anticipated advantages that the biorepository may ultimately 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 project 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., 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.”

Include the Pathology Resource Site PIs, all co-investigators, Network Manager, Pathology Resource Site Coordinators, Consumer Advocate, Data Management Specialist, Data Quality Control Specialist, and other key personnel.

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”

**4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

*As part of the Multiple PI Option, Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PIs. The combined total direct costs for the Initiating and Partnering PIs’ budgets may not exceed \$3M.*

*Note: Budget amounts for the Pathology Network Sites should reflect the resources to be contributed; however, if the budgets differ significantly between Pathology Resource Sites, the differences must be well justified in the budget justification.*

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

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

**Application Components for the Partnering PIs, if applying under the Multiple PI Option:**

*Each Partnering PI must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate his/her grant application package(s) with that of the Initiating PI.*

The application submission process for Partnering PIs uses an abbreviated application package of forms and attachments from Grants.gov that includes:

**1. SF 424 (R&R) Application for Federal Assistance Form**

**2. Attachments Form**

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PIs should be noted for each task.* An example of this type of SOW is available at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

**3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

*As part of the Multiple PI Option, Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PIs. The combined total direct costs for the Initiating and Partnering PIs’ budgets cannot exceed \$3M.*

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

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

**D. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

**E. Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

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

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

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

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

#### **B. Application Review Criteria**

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following equally scored criteria;
  - **Personnel**
    - How well the Coordinating Center PI, Pathology Resource Site PIs, and other key personnel have demonstrated the expertise, experience, and accomplishments to enable successful development, administration, and fiscal management of a biorepository.
    - How the Coordinating Center PI, Pathology Resource Site PIs, and other key personnel have demonstrated previous success in multi-institutional collaborations including past performance of a PCRPs PCPRN Award, if applicable.
    - To what degree the named Network Manager and Pathology Resource Site Coordinators possess the appropriate expertise to coordinate Network activities across all Sites and expedite protocols through regulatory approval processes.

- To what degree the named Data Management Specialist and Data Quality Control Specialist possess sufficient expertise in informatics and data management.
- Whether there are sufficient levels of effort for the successful conduct of the proposed work at each of the institutions involved.
- **Institutional Resources and Commitment**
  - Whether there is evidence of strong commitment from the Coordinating Center and each Pathology Resource Site institution to provide the necessary resources and facilities for the development of a biospecimen repository, its operation in the context of a cooperative network, and allowing biospecimens to be shared with investigators outside the Network.
  - Whether each institution to be involved in the work has unique resources that will benefit the biorepository Network.
  - To what degree the institutions have a demonstrated track record of sharing biospecimens and/or suitable plans to do so.
  - How well the willingness and abilities of the institutions to resolve intellectual and material property issues among participating institutions have been demonstrated.
- **Organizational Structure**
  - To what degree the strategies for the development and implementation of the biorepository at each institution involved are well demonstrated and will facilitate its success.
  - Whether the proposed organizational management plan is appropriate with respect to Network committees, decision making, allocation of resources, coordination of Network functions including regulatory approval processes, and conflict resolution among all participating PIs and institutions.
  - How well one or more consumer advocates have been incorporated into the overall leadership/oversight committees and interaction with the PIs of the Network.
  - Whether there are appropriate plans for oversight by an EAB with qualifications that will provide sufficient oversight and guidance for the success of the biorepository.
- **Operational Management**
  - Whether the proposed plan for coordinated ongoing communication across the Network are appropriately robust.
  - The extent to which appropriate plans for biospecimen distribution to the prostate cancer research community, including evaluation and prioritization of requests for biospecimens, have been included.
  - To what extent 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 Prostate Cancer Pathology Resource Network informatics system with other biorepository informatics systems.
- Whether there are appropriate plans for rapid publication and other public dissemination of data generated by the Network.
- The degree to which the proposed plan for obtaining and marketing biospecimens to the prostate cancer research community will facilitate the success of the biorepository.
- Whether the PI and/or institution has demonstrated sufficient willingness and capabilities to secure additional funds from other agencies to support continued operations of Network.
- **Data Management**
  - 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 structure and data management plans will successfully facilitate prostate cancer research.
  - Whether the plans for data sharing between the Pathology Resource Sites and with the prostate cancer research community, including all data derived from internal and external studies of the biorepository specimens, are sufficient.
- **Legal, Ethical, and/or Regulatory Issues**
  - Whether there are appropriate plans for addressing regulatory issues associated with the legal and ethical 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 there are appropriate plans for the coordination of regulatory submissions and approvals at participating Sites.
  - Whether the plans for ensuring informed consent are sufficiently developed.
- **Participant Access and Recruitment**
  - To what degree 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 excellent capabilities in obtaining high-quality biospecimens.
- **Impact**
  - The extent to which 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 PCRCP overarching challenges and PCRCP 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 project and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

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

- a. **Ratings and evaluations of the peer reviewers**
- b. **Relevance to the mission of the DHP and FY13 PCRCP, as evidenced by the following:**
  - Adherence to the intent of the award mechanism
  - Programmatic relevance in relation to the PCRCP 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 notification of the funding recommendation. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

#### **IV. ADMINISTRATIVE ACTIONS**

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

##### **A. Rejection**

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

##### **B. Modification**

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

##### **C. Withdrawal**

The following may result in administrative withdrawal of the application:

- A FY13 PCRP Integration Panel (IP) member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY13 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel13>.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

#### **D. Withhold**

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

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

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

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

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

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

#### **C. Reporting**

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

If the Multiple PI Option is used, each PI, whether Initiating or Partnering, must submit individual progress reports as required by his or her individual assistance agreement.

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

#### **D. Award Transfers**

The transfer of a Prostate Cancer Pathology Resource Network Award to another institution is not allowed.

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

### **E. Pre-Award Meeting**

At the Government's discretion, the PI and Clinical Study Coordinator or other personnel may be required to participate in a pre-award meeting at the Government's expense.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

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

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

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

Phone: 800-518-4726

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

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## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed (for each applicable PI)
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.		
	Upload Supporting Documentation (Support.pdf) as Attachment 2.		
	Upload Technical Abstract (LayAbs.pdf) as Attachment 3.		
	The Lay Abstract is not required at this time. <b>Leave Attachment 4 space blank.</b>		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Impact Statement (Impact.pdf) as Attachment 6.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
	Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.		