Program Announcement

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Prostate Cancer Research Program (PCRP)

Prostate Cancer Pathology Resource Network Award

Funding Opportunity Number: W81XWH-09-PCRP-PCPRNA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Prostate Cancer Research Program (PCRP) was established in fiscal year 1997 (FY97) to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY08 totaled $890 million (M). The FY09 appropriation is $80M.

The overall goal of the FY09 PCRP is to find and fund innovative, high-impact research relevant to the prevention, detection, diagnosis, and/or treatment of human prostate cancer. Specifically, the PCRP seeks to:

- Support innovative research by individual investigators in multiple disciplines;
- Sponsor multidisciplinary team science to bring together diverse expertise and approaches that will accelerate the conquering of prostate cancer;
- Fund translational research to promote the bench-to-bedside or bedside-to-bench transition between basic and clinical science;
- Foster the next generation of prostate cancer investigators through mentored research and training;
- Promote research into prostate cancer health disparities, including, but not limited to, race and ethnicity, socioeconomic status, access to health care, insurance status, age, geography, and cultural beliefs; and
- Promote research on patient survivorship, life extension, and quality of life.

FY09 PCRP Focus Areas

Imaging: Development of new imaging technology for the detection, prognosis, and treatment of prostate cancer.

Biomarkers: Discovery and validation of biomarkers for the detection, prognosis, and progression of prostate cancer, including determination of therapeutic response.

Therapy: Identification of new targets, pathways, and therapeutic modalities or molecules for the treatment of prostate cancer.

Genetics: Understanding the genetics and epigenetics responsible for prostate cancer susceptibility, disease progression, and treatment outcomes.

Tumor Biology: Understanding the etiology of prostate cancer, including heterogeneity and microenvironment as it relates to initiation, progression and prognosis.

Survivorship: Studies on the impacts of treatment, nutrition, metabolism, and exercise on the well being of prostate cancer patients and their families.

B. Award Description

The PCRP Prostate Cancer Pathology Resource Network Award is intended to provide infrastructure support for the development of a prostate cancer biorepository consortium that will facilitate the collection, processing, annotation, storage, and distribution of high-quality human prostate cancer biospecimens through a collaborative network across multiple institutions. The Network will also collect, store, and manage data derived from the distributed biospecimens. The initial, pilot Network will consist of a Coordinating Center and two additional Pathology Resource Sites that will be jointly responsible for developing the biospecimen repository for prostate cancer research. Additionally, Pathology Resource Network Sites 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.

This award is intended to support Principal Investigators (PIs) with 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. The Prostate Cancer Pathology Resource Network Award mechanism seeks applications from institutions 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 Network Sites for data transfer) in place to support the development of a biorepository. Institutions must demonstrate enhanced access to both patients and patient samples, and the ability to collect high-quality prostate cancer and normal biospecimens from ethnically diverse patient populations across the spectrum of disease stages. This will include collection of biospecimens from disproportionately affected populations to facilitate biomedical research targeted toward resolving prostate cancer health disparities. It is expected that institutions will demonstrate their ability to collect a variety of tumor samples across the spectrum of prostate cancer progression and from the various procurement procedures.

All data generated from the use of biospecimens obtained from the Prostate Cancer Pathology Resource Network biorepository will be deposited into a common information grid. Investigators will first have the opportunity to publish the data, after which (and according to a prescribed period of time determined by the Network and in accordance with journal policies) the dataset will be released for distribution and shared with the prostate cancer research community through an internet-accessible database. Investigators must agree to share their data in order to use biorepository resources. The Prostate Cancer Pathology Resource Network will control access to all repository data. In addition, protocols and methods that were used to derive data from biorepository specimens should be available through an open source system such as public websites.

The Prostate Cancer Pathology Resource Network Coordinating Center**,** in addition to functioning as a Pathology Resource Network Site, will serve as the nexus for Network information and planning, providing administrative, operational, and data management, and provide support to Pathology Resource Network Sites in implementing Network policies and standard operating procedures. The Coordinating Center will have multidisciplinary expertise and extensive experience in multi-institutional collaborations in prostate cancer research. All

Pathology Resource Network Sites must collaborate with the Coordinating Center to develop policies and standards of operation for the entire Network and harmonize the Network informatics grid with the national Cancer Biomedical Informatics Grid (caBIG) and the corresponding tissue bank repository tool, caTissue Core, for biospecimen inventory, tracking, and basic annotation. While it is not expected that Pathology Resource Network Sites will use the caTissue Core, they must be able to input data into the system and be able to interact with it.

Applications for the Coordinating Center of the PCRP Prostate Cancer Pathology Resource Network Award should describe how the development of the Network biorepository will enable the prostate cancer research community to address multiple FY09 PCRP focus areas by utilizing any of the Network services to advance prostate cancer research. These applicants should propose a clearly defined Mission that will guide the proposed Network's biospecimen distribution and data collection processes. In addition, institutions must demonstrate a commitment to secure additional funds from other agencies to continue operations of the Network after the end of the PCRP award performance period.

The Prostate Cancer Pathology Resource Network Award mechanism will be used to select and fund both the Coordinating Center and the Pathology Resource Network Sites. Applicants will be required to indicate whether the application is for the Coordinating Center or a Pathology Resource Network Site. Applicants for the Coordinating Center have the option to be considered for a Pathology Resource Network Site if not selected as the Coordinating Center.

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

Biospecimens: The biorepository will collect, process, annotate, store, and distribute high-quality human prostate cancer and normal tissues and other non-anatomic pathologic samples to include blood, urine, prostatic fluids, and other source genomic and proteomic material. 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, as soon as possible and within the first year of the performance period, standard operating procedures for biospecimen collection methods and post-collection processing, for consideration by Network members.

Clinical Annotation of Biospecimens and Data Quality Assurance: In addition to the importance of high-quality tissue samples, annotation of tissue samples is critical to the success of research studies to be conducted with samples obtained from the biorespository. Within the framework of the data management plan, the Network must develop a plan to establish common data elements and standardized language to annotate tissue samples 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, and (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 will be expected to facilitate a mechanism through which annotated data in the repository is routinely updated. To ensure the quality of the biospecimens and the consistency and accuracy of data in the respository, 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. The Coordinating Center will have a **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.

Informatics and Data Management: It is expected that the Network will develop 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 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 national biorepositories. The Coordinating Center will have a **Data Management Specialist** who will interact and oversee all informatics and data management within the Network. The Data Management Specialist will be a member of the Coordinating Center administrative team.

Informed Consent: Applications for the Prostate Cancer Pathology Resource Network are expected to demonstrate plans for obtaining 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 consents obtained for surgical procedures. This includes specimens collected during routine medical care that will be used for future research purposes.

Network Committees: Within the organizational structure of the Prostate Cancer Pathology Resource Network, the Coordinating Center will serve as the nexus for Network information and planning, providing administrative, operational, and data management. The Coordinating Center will have a **Network Manager** who will assist with daily operations of the Coordinating Center. Similarly, each Pathology Resource Site will have a **Pathology Resource Site Coordinator** who will work with the Coordinating Center Network Manager on Network-wide functions in addition to Site-specific functions. In addition, a Steering Committee composed of Site PIs and/or co-PIs, Coordinating Center key personnel (Network Manager, Data Management Specialist, Data Quality Control Specialist), at least one **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 polices that govern standard operating procedures (in accordance with NCI "Best Practices for Biospecimen Resources" (http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf) to include standards for quality control, specimen collection, processing, annotation, distribution, legal and ethical regulatory issues, polices 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.

Consumer Advocate Participation: Prostate cancer consumer advocates will be an integral part of the Prostate Cancer Pathology Resource Network. Consumer 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. Prostate cancer consumer advocates 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 (oversight committee, symposia, and workshops).

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. It is expected that applications for the Prostate Cancer Pathology Resource Network Award will provide documentary evidence of institutional commitment to allowing specimens collected at Pathology Resource Network Sites to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.

Performance Metrics: The Prostate Cancer Pathology Resource Network Award will be accountable to the following performance metrics, upon which continued funding will be contingent after the first twelve months of the award.

- Each Pathology Resource Network Site must contribute biospecimens from a minimum of 50 patients per year, with the expectation that biospecimen contribution will exceed the minimum requirement. Biospecimens from ethnic minority populations should match or exceed the existing ethnic minority patient population available to the Pathology Resource Network Site. In addition to the primary goal of collecting tissue samples, associated blood, urine, prostatic fluids, and other biological samples should also be collected.

- The Network Coordinating Center must develop standard operating procedures for biospecimen collection methods and post-collection processing, and present them to the Pathology Resource Network Sites. The Network Coordinating Center is expected to provide documentation of these standard operating procedures to the External Advisory Board no later than the end of the first year of performance.

- The Network Coordinating Center must demonstrate sufficient activity with the prostate cancer research community through ongoing documentation of Letters of Intent for utilization of biorepository specimens, to include the number of requests received, approved, or rejected, and the types of specimens distributed. Sites must demonstrate the impact of the biospecimens collected 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, including caBIG.

- Each Pathology Resource Network 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.

External Advisory Board and Prostate Cancer Pathology Resource Network Workshop: An External Advisory Board (EAB) composed of the PCRP Integration Panel (IP), PCRP Program Manager, PCRP Grants Manager, and other experts as appointed by the CDMRP will provide oversight and guidance on the progress of the biorepository. The EAB Chairperson, PCRP Program Manager, and PCRP Grants Manager must be invited to meetings of the Steering Committee. PIs are required to present written and oral annual briefings to the EAB and USAMRMC staff at meetings typically held in the Baltimore-Washington, DC area. Based on these reports and presentations, USAMRMC staff, with recommendations from EAB members, will evaluate progress, provide feedback, and invoke modifications and terminations as needed to facilitate the success of the Prostate Cancer Pathology Resource Network.

The Network awardees will be expected, during the period of performance for the award, to conduct one workshop to convene Network PIs, other biorepository participants, and other experts in the field of biorepositories. The agenda should include discussions on process improvements and new technologies to facilitate the success of the Network biorepository. This workshop should be held in conjunction with one of the required EAB meetings.

Responsibilities of the Consortium Participants: ***Both the Pathology Resource Network Coordinating Center and Sites will be required to attend a Pre-award Planning Meeting.*** Procedures for the consortium, while proposed by the Coordinating Center, will be developed collaboratively and agreed upon by all participants.

a. Coordinating Center: Responsibilities specific to the Coordinating Center include:

- Adherence to the responsibilities delineated below for a Pathology Resource Site.
- Development and maintenance of the Network organizational structure including establishment of committees and participation of one or more prostate cancer consumer advocate(s) (see section above on **Network Committees**).
- Provision of key personnel: Network Manager, Data Control Specialist, Data Management Specialist, and Consumer Advocate who will interact with Pathology Resource Network Sites to coordinate biorepository operational functions.
- Establishment and coordination of policies that govern standard operating procedures (in accordance with NCI "Best Practices for Biospecimen Resources"(http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf), to include standards for data quality control and assurance, biospecimen collection, processing, annotation, and distribution, legal and ethical regulatory issues, polices for review, evaluation, selection and prioritization of specimen distribution, and fees and other costs to investigators for processing, handling, and shipping requests for samples.
- Establishment and management of 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.
- Establishment and management of a communications plan and an ongoing communications system between the Coordinating Center and Pathology Resource Sites.
- Management of Network-developed procedures for biospecimen inventory control, quality assurance, and quality control measures, including:
    - Developing 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.
    - Interim evaluation of quality assurance and control procedures.
- Management of Network-developed 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.
- Management of Network-developed intellectual and material property issues among institutions participating in the Network.

- Management of consortium-developed procedures for the timely release of all data obtained from use of biospecimens following publication of significant findings.
- Development of a plan for securing funds from other agencies to leverage Network resources to continue operation of the Pathology Resource Network beyond the period of performance of the PCRP award.
- Development, organization, and submission of written and oral annual briefings to the EAB and USAMRMC staff.
- Development of a workshop of Network PIs, other biorepository participants, and other experts in the field of biorepositories, to be held in conjunction with one of the required EAB meetings.
- Additional responsibilities based on recommendations and guidance from the Network EAB and USAMRMC staff.

b. Pathology Resource Network Sites: The responsibilities of each Site include:

- Full participation in the Network, including but not limited to contribution of biospecimens from at least the minimum number of 50 patients per year (to include patients from disproportionately affected populations). This will include collection, processing, annotation, storage, and distribution of high-quality human prostate cancer biospecimens, collection and timely submission of research data acquired from specimen use, meeting attendance, and adherence to the Network's operating procedures.
- Provision for a **Pathology Resource Site Coordinator** who will interact with the Coordinators of other Pathology Resource Network Sites and the Network Manager of the Coordinating Center to expedite review, selection, and prioritization of biospecimen distribution, facilitate regulatory approval processes, develop protocols, and coordinate other biorepository activities across Sites.
- Implementation of the Network's informatics system and core data collection methodology and strategies.
- Compliance with Network-developed quality assurance and quality control procedures for biospecimens and biospecimen data as appropriate, including:
    - Participation in an on-site monitoring program to be managed by the Coordinating Center.
    - Implementation of the Network-developed management plan for biospecimen collection, processing, annotation, storage, and distribution.
    - Submission of appropriate data and materials to the Coordinating Center to allow for verification and review of protocol-related procedures, for example, pathology, imaging techniques, surgical methods, and requests for biospecimens.

- Implementation of Network procedures to ensure that requests for use of biospecimens are in compliance with the local IRBs for the conduct of research and the protection of human subjects.
- Participation in Network-developed procedures for the timely publication of research results.
- Participation in Network-developed procedures for resolving intellectual and material property issues among institutions participating in the Network.
- Implementation of the Network-developed plan for securing funds from other agencies to leverage Network resources to continue operation of the Pathology Resource Network beyond the period of performance of the DOD award.
- Attendance at a Pre-Award Planning Meeting with all Network members to begin development of Network operational features, discuss the requirements for progress and evaluation, and facilitate the award negotiations process.
- Presentation of written and oral annual briefings to the EAB and USAMRMC staff.
- Participation in a workshop of Network PIs, other biorepository participants, and other experts in the field of biorepositories organized by the Coordinating Center.
- Preparation for site visits by the government or its designee, if required.
- Additional responsibilities based on recommendations and guidance from the Network EAB and USAMRMC staff.

C. Eligibility

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).

Refer to Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- **Coordinating Center with Pathology Resource Network Site**
  - The period of performance for this award is 3 years.
  - The maximum allowable funding for the entire period of performance is **$1,300,000** in total direct costs, to include:
    - **$700,000** maximum in direct costs for all Coordinating Center functions as described in this Program Announcement/Funding Opportunity, plus

        - **$600,000** maximum in direct costs for all Network Site functions as described in this Program Announcement/Funding Opportunity.
    - In addition to the direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement.

- **Pathology Resource Network Sites (only)**
    - The period of performance for this award is 3 years.
    - The maximum allowable funding for the entire period of performance is **$600,000** in direct costs. These funds are for all Network Site functions as described in this Program Announcement/Funding Opportunity.
    - In addition to the direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- 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 of the entire budget)
- 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
- Travel to EAB meetings
- Planning and travel costs for Network workshops
- Travel to a Network Pre-Award Meeting in the Baltimore-Washington DC area

In addition, funding must be requested for the PI of each Pathology Resource Site and the Coordinating Center to travel to **one** PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting.

The CDMRP expects to allot approximately $3.8M of the $80M FY09 PCRP appropriation to fund one Coordinating Center and three Prostate Cancer Pathology Resource Network Sites, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

E. Award Administration

The Prostate Cancer Pathology Resource Network Award cannot be transferred to another institution. Refer to the Application Instructions and General Information, Appendix 5, for general award information on changes in award personnel or institution.

PIs will be required to submit quarterly written progress reports and a final written comprehensive report.

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

II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission. ***Pre-application submission is a required first step***.

Pre-application Submission Deadline:	**July 15, 2009, 5:00 p.m. Eastern Time**
Application Submission Deadline:	**August 5, 2009, 11:59 p.m. Eastern time**
Scientific Peer Review:	**September 2009**
Programmatic Review:	**November 2009**

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/), and (2) an application submission through Grants.gov (http://www.grants.gov/).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at: help@cdmrp.org or 301-682-5507.

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative applications.

A. Step 1 – Pre-Application Components and Submission

Pre-application submission is the required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by ***5:00 p.m. Eastern time on the deadline date***. In

addition to award-specific information provided below, refer to the Application Instructions and General Information for detailed information on pre-application components and submission.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2 – Application Components and Submission

Applications will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

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

2. **Attachments Form**

   - Attachment 1: Project Narrative (60-page total limit for the Coordinating Center (30 pages) plus Pathology Resource Network Site (30 pages), 30-page limit for Pathology Resource Sites only)

   All applications for the PCRP Prostate Cancer Pathology Resource Network Award must indicate if the application is being submitted for consideration as a:

   - Prostate Cancer Pathology Resource Network Site,
   - Coordinating Center, or
   - Coordinating Center with the option to be considered as a Prostate Cancer Pathology Resource Network Site if the proposal is not selected for award as the single Coordinating Center.

   Describe the proposed project in detail using the outline below**.**

   a. Coordinating Center: It is the PI's responsibility to clearly articulate the ability of his or her institution to serve as the Network Coordinating Center and support the development, administration and fiscal management of a Network biorepository.

   i. 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 communications systems and data management resources for multi-institutional projects. Reference relevant publications and submit reprints with the proposal.

ii. Coordinating Center Organizational Structure

Include in the description of the organizational structure the following key features:

- Describe the organizational structure, how standard operating procedures will be developed for collection, processing, annotation using standardized language, storage, and distribution of prostate cancer and normal biospecimens across the spectrum of disease stages and from ethnically diverse and disproportionately affected populations in accordance with the NCI's "Best Practices for Biospecimen Resources."
- Coordinating Center plans for administration and day-to-day management of Network operations;
  - 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;
  - 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.
- The involvement of a **prostate cancer consumer advocate**. Provide a **named** consumer advocate to serve as a member of the Steering Committee, and describe the consumer advocate's familiarity with current issues in prostate cancer. Describe how prostate cancer consumer advocate(s) will play an active role in the Pathology Resource 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.

iii. Institutional Resources

- 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 Network 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.
- The unique capabilities and strengths of the institution to serve as a Coordinating Center for the Prostate Cancer Pathology Resource Network.

iv. Operational Management

- Provide evidence of the expertise of all key personnel that will be involved in the Coordinating Center and 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 three Sites to coordinate activities across all Sites, including interacting with Pathology Resource Network Site Coordinators to expedite protocols through regulatory approval processes, expedite review, evaluation, selection, and prioritization of specimen distribution, develop protocols, and coordinate patient participation and other biorepository activities across Sites.
- Include a **named Data Quality Control Specialist** who will interact with all Pathology Resource Network 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.
- Communication and Network Interaction: Describe the communication plan between the Coordinating Center and Pathology Resource Network 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.
- 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 including caBIG and caTissue.
- 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.

v. Biospecimen Management, Quality Assurance, and Distribution

Include in the description of the biospecimen management and quality assurance the following key features:

- 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.

vi. Informatics and Data Management

Describe plans to develop comprehensive data management, to include the following:

- A **named Data Management Specialist** who will interact with all Pathology Resource Network Site Coordinators to optimize informatics and data management within the Network.
- A description of 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.
- The overall planned approach to data collection and management.
- A plan for ongoing data transfer, security, and integrity.
- A plan for managing the resources of the Network while remaining current and responsive to non-Network prostate cancer investigators.
- A plan for sharing all data derived from Network biorepository specimens, whether generated by Network or non-Network investigators.

vii. Legal, Ethical, and Human Subject Issues

Include in the description of the legal, ethical, and human subject issues the following key features:

- 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.

viii. Financial Management and Marketing of Resource Specimens

- Describe how the PI/institution intends to secure funds from other agencies to leverage Network resources to continue operation of the Pathology Resource Network during and 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.

b. All Sites (Coordinating Center and Pathology Resource Network Sites): It is the responsibility of the PI to clearly articulate the expertise, experience, and resources (including necessary equipment and access to patient populations) of the PI, personnel, and institution to participate as a Pathology Resource Network Site of the Consortium.

i. Experience and Expertise in Multi-Institutional Collaboration and Biorepository Development: Describe the PI's previous experience and accomplishments in multi-institutional collaboration. Describe the expertise, experience, and accomplishments related to the development, administration, and fiscal management of a biorepository. Describe previous experience with collaborative communication systems and data management resources for multi-institutional projects. Reference relevant publications and submit reprints with the proposal.

ii. Pathology Resource Network Site Organizational Structure

Include in the description of the organizational structure the following key features:

- Descriptions of the organizational structure of the Pathology Resource Network Site, including plans for collecting, processing, annotating using standardized language, storing, and distributing prostate cancer and normal biospecimens across the spectrum of disease stages and from ethnically diverse and disproportionately affected populations.
- Plans for administration and day-to-day management of Network Site:
  - Coordination and development of protocols, equipment, and training of personnel;
  - Coordination of regulatory issues;
  - Coordination and oversight of privacy and confidentiality of patient data; and
  - Management and monitoring of biospecimen processing, annotation, storage, and distribution.
- The involvement of prostate cancer consumer advocate(s). Describe plans to include prostate cancer consumer advocate(s) in Pathology Resource Network Site operations. Appropriate integration of consumer advocates at Pathology Resource Network Sites may include attendance at Network-related meetings, 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.
- Description of information technologies that will be used to facilitate routine communication, and information and data sharing with the Coordinating Center and other Network Sites.

iii. Pathology Resource Network Site Resources

- Provide evidence of the expertise of all key personnel that will be involved in the Network Site and describe their expected roles as they relate to the collection, processing, annotation, storage, and distribution of human prostate biospecimens across the Network. Key personnel must include a

named Pathology Resource Network Site Coordinator, who will interact with the Pathology Resource Network Site Coordinators at other Pathology Resource Network Sites and the Pathology Resource Network Manager at the Coordinating Center to expedite review, evaluation, selection, and prioritization of specimen distribution, expedite regulatory approval processes, develop protocols, coordinate personnel training, and coordinate patient accrual and other biorepository activities.

- 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 samples across the spectrum of disease stages and from ethnically diverse and disproportionately affected populations.

iv. Institutional Resources

- 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 Network Sites to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.
- Describe the unique capabilities and strengths of the institution to serve as Prostate Cancer Pathology Resource Network Site

v. Biospecimen Management, Quality Assurance, and Distribution

Include in the description of the biospecimen management and quality assurance the following key features:

- A plan for biospecimen management, to include methods for biospecimen collection, tracking, storage, integrity, transport distribution, and security that will be proposed to the Coordinating Center for adoption by the entire Prostate Cancer Pathology Resource Network.
- Descriptions of quality control measures for biospecimens, biospecimen data, and monitoring of biospecimens to avoid sample variability.
- A plan for collecting and ensuring the quality of pathological and clinical biospecimen data and research data analyses.
- A plan for serving as one of the entry points for biospecimen and biospecimen requests.

vi. Data Management

- 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 Network Site while remaining current and responsive to non-Network prostate cancer investigators.
- Provide a plan for sharing all data derived from Network biorepository specimens, whether generated by Network or non-Network investigators.

vii. Legal, Ethical, and Human Subject Issues

Include in the description of the legal, ethical, and human subject issues the following key features:

- Description of procedures for ensuring compliance with ethical and legal involvement of human subjects, and issues involved in the collection and use of biospecimens in research;
- Include a description of the methods for obtaining informed, tiered patient consent to include clinicians, surgeons, and other personnel necessary for the consent process. The plan should address routine medical care and surgical procedures and patient confidentiality. The methods proposed should be substantive such that they could be proposed as a model to the Coordinating Center for adoption by the entire Prostate Cancer Pathology Resource Network.

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publications and/or Patent Abstracts (ten-document limit for Coordinating Center plus Pathology Resource Network Site, five-document limit for Pathology Resource Network Sites only)
  - Letters of Institutional Support

    Provide letters of institutional support, signed by senior administrators (e.g., Vice President, Cancer Center Director, Dean) that reflect the institution's commitment to provide the facilities and resources to participate in 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 Network Sites to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.
  - Letters of Collaboration (if applicable)
    1. 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.
    2. 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 samples, 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.
    - Intellectual and Material Property Plan

      Provide a plan for resolving intellectual and material property issues among participating institutions, and for how Material Transfer Agreements (MTA) will be established.

- Attachment 3: Public Abstract
- Attachment 4: Statement of Work (SOW)
- Attachment 5: Pathology Resource Network Site Detailed Budget and Justification
- Attachment 6: Impact Statement

  Describe how the proposed Coordinating Center and/or Pathology Resource Network Site will have a significant contribution to the biorepository Network as a resource, and impact the progress in prostate cancer research toward conquering the disease.

- Attachment 7: Focus Area Statement

  Describe the extent to which the proposed Coordinating Center and/or Pathology Resource Network Site will enable prostate cancer research investigators to address multiple FY09 PCRP focus areas toward the goal of advancing prostate cancer research.

- Attachment 8: Federal Agency Financial Plan (if applicable)
- Attachment 9: Coordinating Center Detailed Budget and Justification (if applicable)
- Attachments 10-15: Subaward Detailed Budget and Justification (if applicable)

3. Research & Related Senior/Key Person Profile (Expanded Form)

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)

  Coordinating Center with Pathology Resource Network Site*:* Include all co-investigators, Network Manager, Pathology Resource Network Site Coordinator, Consumer Advocate, Data Management Specialist, Data Quality Control Specialist, and other key personnel.

  Pathology Resource Network Site: Include all co-PIs, Pathology Resource Network Site Coordinator, and other key personnel.

- Key Personnel Current/Pending Support

4. Research & Related Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application 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 institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement or Impact Statement).

B. Review Criteria

1. **Peer Review:** All applications will be evaluated according to the following criteria.

   a. Coordinating Center (to be reviewed in addition to the All Sites criteria below): All Coordinating Center applications will be evaluated according to the following criteria. Of these, Personnel, Institutional Resources and Commitment, Network Organizational Structure, and Operational Management are equally the most important, with the remaining criteria listed in decreasing order of importance.

   - **Personnel**
     - Whether the PI meets the eligibility requirements.
     - How well the PI or other key personnel have demonstrated the required expertise, experience and accomplishments related to the development, administration, and fiscal management of a biorepository.

- Whether the PI and key personnel have previous success in multi-institutional collaborations.
- Whether the named Network Manager, who will interact with all Pathology Resource Network Site Coordinators, possesses the appropriate expertise to coordinate Network activities across all Sites and expedite protocols through regulatory approval processes.
- Whether the named Data Management Specialist and Data Quality Control Specialist possess sufficient expertise in informatics and data management.

- **Institutional Resources and Commitment**
  - Whether there is evidence of a strong institutional commitment to providing the necessary resources and facilities for the development of a biospecimen repository and its operation in the context of a cooperative network, and allowing biospecimens to be shared with investigators outside the Network.
  - The degree to which other institutional resources will be available to contribute to the success of the biorepository.
  - Whether the plans to resolve intellectual and material property issues among participating institutions are feasible.
- **Network Organizational Structure**
  - The degree to which the strategies for the development and implementation of the biorepository 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 consumer advocates have been incorporated into the overall leadership/oversight committees and interaction with the PIs of the Network.
- **Operational Management**
  - Whether the proposed plan for coordinated ongoing communication across the Network using the most current technologies would be effective.
  - The extent to which appropriate plans for biospecimen distribution to the prostate cancer research community, including evaluation and prioritization of requests for biospecimens, are demonstrated.
  - Whether 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 national biorepository informatics systems including caBIG and caTissue.

- Whether there are appropriate plans for rapid publication and other public dissemination of data generated by the consortium.
- 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.
- 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.

- **Data Management**
  - Whether the plans for sample collection and annotation are appropriately robust to provide data sufficient for a large range of significant prostate cancer studies.
  - How the strategies for the development and implementation of a data management plan will provide adequate access to data, data security, 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.
- **Regulatory Process**
  - How well the PI outlines a process that will govern legal, ethical, and human subject issues and the use of human biospecimens in research.
  - Whether there are appropriate plans for the coordination of regulatory submissions and approvals at participating Sites.
  - Whether the plans for obtaining patient informed consent are sufficiently developed.

b. All Sites (Pathology Resource Network Sites and Coordinating Center): All applications will be evaluated according to the following criteria. Of these, Personnel, Participant Access and Recruitment, Institutional Resources and Commitment, and Organizational Structure, are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Personnel**
  - Whether the PI meets the eligibility requirements.
  - How the prostate cancer research and biorepository expertise of the PI(s) and supporting investigators will facilitate the success of the Pathology Resource Network Site and the Network as a whole.
  - Whether there are sufficient levels of effort for the successful conduct of the proposed work for the Pathology Resource Network Site.
  - How well the PI has demonstrated a successful track record of collaboration with other investigators.

- Whether the PI(s) and Pathology Resource Network Site Coordinator possess appropriate expertise in obtaining regulatory approvals.
- Whether the named Pathology Resource Network Site Coordinator has the experience to coordinate activities with other Network Sites and the ability to foster communication with other Pathology Resource Network Site Coordinators.

- **Participant Access and Recruitment**
  - Whether the PI has demonstrated enhanced access to diverse patient populations and/or patient samples that include the spectrum of disease stages.
  - 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.
- **Institutional Resources and Commitment**
  - Whether the institution has unique resources that may be of benefit to the Prostate Cancer Pathology Resource Network.
  - Whether there is evidence of a strong institutional commitment to providing the necessary space and facilities for biospecimen handling and storage.
  - The degree to which other institutional resources will be available to contribute to the success of the biorepository.
  - Whether the institution has a demonstrated track record of sharing biospecimens and/or suitable plans to do so.
  - How well the institution has demonstrated its willingness and ability to resolve intellectual and material property issues with other institutions in the Network.
- **Organizational Structure**
  - The degree to which the proposed organizational structure is appropriate for the development of a Pathology Resource Network Site.
  - Whether the proposed organizational structure is sufficient to contribute substantially to ongoing Prostate Cancer Pathology Resource Network biorepository functions; and whether the team's background and expertise suggest that they can perform multi-institutional collaboration.
  - Whether there are sufficient plans to integrate consumer advocates into Pathology Resource Network Site operations and interaction with the PI and other personnel of the Pathology Resource Network Site.
- **Data Management**
  - Whether the PI has provided evidence of adequate resources for ongoing data transfer, management and maintenance of data security/confidentiality.

- How well the PI has demonstrated capabilities to remain current and responsive to non-Network investigators by the existing or proposed information systems to manage Pathology Resource Network Site resources.
- Whether the plans for data sharing between the Pathology Resource Network Sites and with the prostate cancer research community, including all data derived from internal and external studies of the biorepository specimens, are sufficient.

- **Collaborations**
  - How the expertise and resources of the PI and institution are ideal for a collaboration to create a biorepository Site that will best facilitate prostate cancer research.
  - How well the PI will integrate into the Network and be a contributing member.
  - How well the PI's institution has facilitated the PI's collaborations.
  - How well the application outlines the unique contributions of the PI and institution to the overall project.
- **Impact**
  - The extent to which the proposed Pathology Resource Network Site, if successful, will have a significant contribution to the biorepository Network as a resource, and impact the progress on prostate cancer and/or prostate cancer research.
- **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 obtaining informed consent are well described and sufficiently address patient confidentiality.
  - Whether the plans for data acquisition and storage will sufficiently maintain patient confidentiality.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

- **Responsiveness to Focus Area(s)**
  - The extent to which the proposed Pathology Resource Network Site will enable prostate cancer investigators to respond to multiple FY09 PCRP focus areas toward the goal of advancing prostate cancer research.
- **Budget**
  - Whether the budget is appropriate for the proposed project and within the limitations of the award mechanism.

- **Application Presentation**
    - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria will be used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative collaboration and impact
- Program portfolio balance

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, USAMRMC.

V. 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:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- ***NEW for FY09:*** Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided by 5:00 p.m. Eastern time on the second full business day following the date the email was sent. Otherwise, the application will be reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved 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 FY09 IP members may be found at http://cdmrp.army.mil/pcrp/panel09
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.

D. Withhold

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

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079

Fax: 301-619-7792

Email: cdmrp.pa@amedd.army.mil

B. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507

Website: https://cdmrp.org

Email: help@cdmrp.org

C. Grants.gov contacts: Questions related to application submission through the Grants.gov (http://www.grants.gov/) portal should be directed to the Grants.gov help desk. Deadlines for application submission are 11:59 p.m. Eastern time on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: support@grants.gov

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or Application Package ONLY if the PI subscribes to the mailing list by clicking on the "send me change notification emails" link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.