Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Impact Award

Funding Opportunity Number: W81XWH-11-PCRP-IA
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)**,** June 10, 2011
- **Invitation to Submit an Application:** July 13, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, September 1, 2011
- **Scientific Peer Review:** October 2011
- **Programmatic Review:** December 2011

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

TABLE OF CONTENTS

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Prostate Cancer Research Program (PCRP) was established in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY10 totaled $1.05 billion. The FY11 appropriation is $80 million (M).

The overall goal of the FY11 PCRP is to find and fund innovative, high-impact research that will eliminate death and suffering from prostate cancer. Specifically, the PCRP seeks to support innovative, high-risk, high-gain research with potential near-term impact; sponsor multidisciplinary synergistic research; fund translational studies to promote the fluid transfer of knowledge between bedside and bench; invest in research on patient survivorship (quality of life); foster the next generation of prostate cancer investigators through mentored research; and, promote research into prostate cancer health disparities.

PCRP Overarching Challenges

Consistent with the program's overall goal, each PCRP funding opportunity either requires or encourages (see Award Information below) applications to address one of the following PCRP overarching challenges:

- Develop effective treatments for advanced prostate cancer (i.e., disease relapse with no available curative therapy)
- Distinguish aggressive from indolent disease

PCRP Focus Areas *(revised for FY11)*

All applications for FY11 PCRP funding opportunities should also address at least one of the following PCRP focus areas:

Biomarkers: Discovery and validation of biomarkers for the detection, prediction of response to therapy, prognosis, and progression of prostate cancer.

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

Imaging: Development of new anatomic and molecular imaging technology for the detection and management of prostate cancer.

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

Therapy: Identification of new targets, pathways, and therapeutic modalities, including immunotherapy and mechanisms of resistance.

Tumor Biology and Immunology: Understanding prognosis and progression of prostate cancer.

B. Award Information

The PCRP Impact Award mechanism was first offered in FY10. Since then, 22 Impact Award applications have been received, and 3 have been recommended for funding.

The PCRP Impact Award supports research projects specifically focused on making a major impact on one critical issue in prostate cancer: reducing or eliminating the over-treatment of primary prostate cancer. Projects funded by this award will, if successful, ultimately change the standard of practice for decision-making in the treatment of primary prostate cancer. ***As such, it is expected that all projects for the Impact Award will address the PCRP overarching challenge to "distinguish aggressive from indolent disease."***

Studies conducted under the Impact Award may include the wide spectrum of basic to clinical research, including clinical trials, provided the overall project is hypothesis-based, focused on the problem of prostate cancer over-treatment, and includes a sound overall research strategy. It is anticipated that studies supported by this award will facilitate assessment of the decision-making process for early stage prostate cancer using clinically relevant endpoints such as clinical progression, need for treatment, and/or other endpoints.

Research proposed under the Impact Award may include, but is not limited to, the following areas that will address the over-treatment of primary prostate cancer:

- Development of surveillance mechanisms, including improvements in current clinical and diagnostic tools to monitor prostate cancer patients (e.g., to standardize inclusion/exclusion criteria)
- Biomarkers to inform decision-making
- Genetic analyses to inform decision-making
- Improved staging, to include imaging
- Optimal measures to inform decision-making pre- and post biopsy
- Optimal measures for follow-up and assessment of progression
- Cancer care outcomes research (e.g., quality of life, survivorship) and surveillance

In addition, Principal Investigators (PIs) are expected to address the following considerations, if applicable:

- For studies using ***model systems*** (e.g., cell animal), include strong justification for why the hypothesis cannot be tested in humans and how the results can be expeditiously validated in a predetermined source of human samples.
- For studies designed from ***population-based perspectives***, include a clearly defined population and evidence of appropriate access to the population (and/or access to available samples/data or database(s) to immediately initiate the project).
- For ***clinical*** studies, include longitudinal follow-up to differentiate, at the time of diagnosis, between patients whose disease is indolent and those whose disease will progress to the aggressive phenotype.

PIs applying for the PCRP Impact Award are expected to establish a multi-disciplinary study team that possesses an appropriate level of prostate cancer-related expertise and may include a variety of clinical specialists to effectively address the proposed question. ***PIs whose study designs require human specimens are encouraged to collaborate with personnel affiliated with established prostate cancer biorepositories.*** A robust statistical plan and statistical expertise should be included in the proposed investigation as well as demonstrated access to, and availability of all samples and data necessary for the study so that the project can commence immediately after an award is made. Study teams for clinical trials must include a Study Coordinator who will guide the clinical protocol through IRB review and other regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate human subject accrual.

Applications must include preliminary data to support feasibility of the study. Any unpublished, preliminary data provided should originate from the laboratory of the PI or member(s) of the research team.

Research involving human subjects, including clinical trials, is permitted under this Program Announcement/Funding Opportunity. If the proposed study involves clinical research (including clinical trials), it is expected that regulatory approval will be obtained and the research initiated within the first year of the award. A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical trials, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/.

It is the intent of the PCRP Impact Award that data and research resources generated by funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. Each proposal should include a data- and/or research resource-sharing plan describing how unique and/or final research data will be shared, along with any resulting research resources. This information should be provided as the Data- and Research Resource-Sharing Plan as described in Section II.C., Application Submission Content and Form, of this Program Announcement/Funding Opportunity. Refer also to the General Application Instructions, Appendix 4, for more information.

C. Eligibility Information

- The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **5** years.
- The maximum allowable direct costs amount for the entire period of performance is **$750,000** plus indirect costs**.**
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **5** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel to one 3½-day PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting, which is held to disseminate the results of PCRP-sponsored research.

May be requested for:

- Salary
- Research supplies
- Research-related human subject costs
- Clinical research costs
- Equipment
- Purchase of datasets and/or databases
- Travel between collaborating organizations
- Travel costs of up to $3,600 per year to attend scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $2.4M of the $80M FY11PCRP appropriation to fund approximately 2 Impact Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

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

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

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-11-PCRP-IA.

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/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507. Changes in PI or organization after submission of the pre-application will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/ Grants Officer.

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 (COI) – Tab 3**
- **Required Files – Tab 4**

  Preproposal Narrative (two-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Rationale:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations.
- **Impact:** Describe the potential of the proposed study to have a transformative impact towards reducing or eliminating the over-treatment of primary prostate cancer.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached. Clearly describe how the research question addresses an issue of critical significance to the problem of over-treatment of prostate cancer.
- **Research Strategy:** Concisely describe the project's specific aims.
- **Research Team:** Describe the composition and expertise of the research team and how these features will facilitate the success of all aspects the project.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

- References Cited (one-page limit): List relevant references 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). The inclusion of Internet URLs to references is encouraged.
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Biographical Sketches for the PI and Key Personnel (four-page limit per individual)

- **Submit Pre-application – Tab 5**
- **Other Documents Tab**

  No additional documents are required**.**

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the Department of Defense (DOD) and CDMRP, pre-applications will be screened by the PCRP Integration Panel (IP) based on the criteria shown below.

  - **Adherence to the Intent of the Award Mechanism:** To what degree the proposed research could, if successful, make a ***major*** impact on reducing or eliminating the over-treatment of primary prostate cancer.

- **Research Strategy:** How well the rationale and specific aims support the project's objective(s).

- **Personnel:** To what degree the research team's background and prostate cancer-related expertise are appropriate with respect to its ability to successfully complete the proposed work, including whether there is evidence of sufficient clinical and/or statistical expertise, if applicable.

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

  Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. Pre-application notification dates are indicated on the title page of this Program Announcement/ Funding Opportunity.

C. Application Submission Content and Form

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

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

Grants.gov application package components: For the Impact 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 (15-page limit):** Upload as "ProjectNarrative.pdf."

     Describe the proposed project in detail using the outline below. Throughout the Project Narrative, clearly convey how the proposed research, if successful, would have a major impact on the over-treatment of primary prostate cancer.

     - **Background:** Present the ideas and reasoning behind the proposed research and include a literature review, preliminary studies and/or preclinical data that led to the development of the proposed clinical trial; unpublished preliminary data should originate from the laboratory of the PI or collaborators named on this application. Describe previous experience most pertinent to this proposal.

     - **Hypothesis:** State the hypothesis to be tested or the objective to be reached.

- **Specific Aims:** Explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Research Strategy:** The research strategy should be based on sound scientific rationale, outlined in detail, and fully supported by the preliminary data and published reports. Describe the experimental design, methods, and analyses. Include a description of appropriate controls and endpoints to be tested, if applicable. Address potential problem areas and present alternative methods and approaches. Statistical analyses appropriate to the type of study (e.g., power analysis for population-based studies) should be well described.
- **Clinical Studies (if applicable):** If the proposed clinical study is prospective, discuss plans for initiating the clinical study within the first year of the award. Provide a properly powered statistical plan and information demonstrating that a sufficient number of participants will be accrued to the proposed study during the award period. ***Include a clear and detailed description of the ethical issues (e.g., informed consent, information privacy, assessment of risk versus benefit of participation) raised by the proposed study, and provide a detailed plan for how the ethical issues will be addressed. If appropriate, include information on whether the study will be subjected to Institutional Review Board (IRB) review.*** The PI or research team must demonstrate appropriate expertise in conducting clinical studies.
- **Strategic Plan:** Provide an overall strategic plan for completing the proposed project. ***If the entire project will not be completed during the performance period of the award, provide evidence that sufficient funds will be available to complete the project.*** For prospective clinical studies, describe and/or provide evidence that the research can be initiated within the first year of the award.
- **Research Team:** Describe the expertise and specific contributions of the multidisciplinary research team that will enable the success of the proposed project.

- **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. ***Each component has no page limit unless otherwise noted.***
  - 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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference

should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. 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, reflecting the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that describes how he/she will support the project, to include:
  - Unique expertise,
  - Availability of and access to research resources, and/or
  - Availability of and access to appropriate populations (and/or access to available samples/data or database[s]) (if applicable).
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  Describe the proposed research project, including the following elements: Background, Objective/Hypothesis, Study Design and Specific Aims, and Impact. The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

- **Attachment 4: Public Abstract (one-page limit):** Upload as "PublicAbs.pdf."

  Public abstracts should be written using the outline below. Do not duplicate the technical abstract. The public abstract is used by consumer reviewers along with other components of the application package.

  - Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine*.**
  - Describe the ultimate applicability of the research**.**
    - What types of patients will it help, and how will it help them?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.

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

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

  Describe the short-term impact: Detail the anticipated results/outcome(s)/ product(s) that will be directly attributed to the results of the proposed research.

  Describe the long-term impact: Explain the anticipated long-term gains from the proposed research, including how the new understanding may ultimately contribute to reducing or eliminating the problem of over-treatment of primary prostate cancer.

- **Attachment 7: Data- and Research Resource-Sharing Plan (one-page limit):** Upload as "SharingPlan.pdf."

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

  The precise content of the data- and research resource-sharing plan will vary, depending on the data being collected, the resources being developed, and how the investigator is planning to share the data and research resources. Applicants should describe the expected schedule for sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing/material transfer agreement (or other documentation) will be required, and if so, a brief description of such an agreement (including the criteria for deciding who can receive the data/research resource and whether or not any conditions will be placed on their use), and the mode of sharing (e.g., posting data on their institutional or personal website, through a data archive or enclave). Investigators should follow their institution's technology transfer policies and provide links to model technology transfer agreements used by their institution, as appropriate.

  If the research involves human subjects and the data and/or research resource(s) are intended to be shared, the application should discuss how the rights and confidentiality of participants would be protected.

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

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

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
- Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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

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

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

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

D. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall 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. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) 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 compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DOD and CDMRP, 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 meritbased selection process. Each level 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. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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).

B. Application Review Criteria

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

   - **Impact**
     - To what degree the potential gains of the proposed project will have a major impact on reducing or eliminating over-treatment of primary prostate cancer.
   - **Research Strategy and Feasibility**
     - How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and logical reasoning.
     - How well the hypotheses or objectives, aims, clinical and other appropriate endpoints (as applicable), experimental design, methods, and analyses are developed and integrated into the project.
     - If cell and/or animal model systems will be used, how well the PI has justified why the hypothesis cannot be tested in humans, and how the results can be expeditiously validated in a predetermined source of human samples.
     - How well the PI acknowledges potential problems and addresses alternative approaches.
     - Whether the application includes an appropriate statistical plan with power analysis (if applicable).
     - Whether the PI has provided sufficient evidence to support availability of and access to the populations/samples required for the study (if applicable).
     - Whether the PI has provided sufficient evidence that resources will be available to complete longitudinal follow-up beyond the period of performance (if applicable).
     - For clinical studies, whether the PI has sufficiently demonstrated that the research can be initiated within the first year of the award.
   - **Personnel**
     - To what degree the research team's background and prostate cancer-related expertise are appropriate with respect to its ability to perform the proposed

work, including whether there is evidence of sufficient clinical and/or statistical expertise.

- To what degree the levels of effort are appropriate for successful conduct of the proposed work.

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

- **Ethical and/or Regulatory Issues**
  - If applicable, whether there is evidence that the PI and research team have appropriately considered and developed a plan to address ethical issues (e.g., informed consent, information privacy, assessment of risk versus benefit of participation) raised by the proposed study.
- **Environment**
  - To what degree the scientific environment is appropriate for the proposed research.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements).
  - To what degree the quality and extent of organizational support are appropriate for the proposed research.
- **Data- and Research Resource-Sharing Plan**
  - To what degree the plan for sharing the study results and resources, if applicable, as widely as possible is appropriate and will facilitate continued research on resolving the critical problem of prostate cancer over-treatment.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

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

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

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. PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

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

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

B. Modification

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

C. Withdrawal

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

- FY11 PCRP IP member 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 FY11 PCRP IP members may be found at http://cdmrp.army.mil/pcrp/panels/panel11.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- 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 and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/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, 2012. 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 C, for general information regarding administrative and national policy requirements.

C. Reporting

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

D. Award Transfers

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

E. Pre-Award Meeting

At the Government's discretion, the PI and Clinical Study Coordinator for any study that includes a clinical trial may be requested to participate in a pre-award meeting.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements and 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: 1-301-682-5507

Email: 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: 1-800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Data- and Research Resource-Sharing Plan (SharingPlan.pdf) as Attachment 7.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI 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 Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete form 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.	