

Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Population Science Impact Award

Funding Opportunity Number: W81XWH-13-PCR-PSIA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

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

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

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

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

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

PCRP Overarching Challenges (*revised for FY13*)

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

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

PCRP Focus Areas (*revised for FY13*)

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

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

- **Mechanisms of Resistance:** Understanding primary and acquired resistance to therapy
- **Survivorship and Palliative Care:** Improving the quality of life and well-being of prostate cancer patients and their families
- **Therapy:** Identification of new targets, pathways, and therapeutic modalities
- **Tumor and Microenvironment Biology:** Understanding the intrinsic and extrinsic mechanisms contributing to tumor development and the progression of prostate cancer

B. Award Information

The PCRP Population Science Impact Award (PSIA) mechanism was first offered as the Population-Based Idea Development Award in FY09 and Population-Based Research Award in FY10 and FY11. In total, 62 applications have been received, and 4 have been recommended for funding.

The Population Science Impact Award mechanism supports high-impact, population science approaches to prostate cancer research. *Applications should clearly demonstrate the potential of the study to contribute significantly to the elimination of death from prostate cancer and/or enhancing the well-being of men experiencing the impact of the disease.* As such, studies should address one of the PCRP overarching challenges, or, alternatively, justify the study as addressing another critical area in prostate cancer research. In addition, studies are expected to address one or more of the PCRP focus areas; for the PSIA, projects focused on the following are particularly encouraged: biomarkers, especially those relevant to aggressive disease; genetics/genomics; therapy and predictors of response or resistance; and survivorship and palliative care. Studies that, in whole or in part, address disparities in prostate cancer incidence, morbidity, or mortality, are also encouraged.

The overall goal of this award is to generate data and/or tools that can only be achieved from the perspective of systematic studies focused on specific populations of individuals, rather than specific individuals. Such studies will be built upon the logic, concepts, and methods of one or more population sciences including but not limited to:

- Epidemiology
- Surveillance
- Health services research
- Outcomes research
- Behavioral science
- Social science
- Dissemination research

The outcomes for research supported through this award mechanism will have the potential for substantial impact for men with or at risk for prostate cancer within, for example, epidemiologic cohorts, defined communities, or health systems.

Applications may propose retrospective, prospective, case control, cohort, or other population science study designs (including the use of biospecimens and data from established retrospective databases), provided the proposed sample is of sufficient size to demonstrate statistical significance. The study should address a well-developed hypothesis that is conceptually sound and specific for prostate cancer. The statistical expertise of the study team should be clearly described and evident in the study plan. Applicants are expected to provide documentation demonstrating access to, and ability to recruit as applicable, the appropriate population(s), patient samples, datasets in numbers sufficient to achieve statistical significance.

Research involving human subject use is permitted under this funding opportunity, but is restricted to studies without clinical trials; however, correlative studies with populations from existing clinical trials, are allowed. For definitions and other information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/.

All investigators applying to FY13 PCRFP funding opportunities are encouraged to consider leveraging resources available through the PCRFP-funded Prostate Cancer Biorepository Network (PCBN) (<http://www.prostatebiorepository.org>) and/or the North Carolina – Louisiana Prostate Cancer Project (PCaP) (<http://www.ncla-pcap.org>), if retrospectively collected human anatomical substances or correlated data are relevant to the proposed studies.

The CDMRP intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

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.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **4** years.
- The maximum allowable direct costs for the entire period of performance are **\$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 **4** 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.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for attendance at one Department of Defense (DoD) PCRP Innovative Minds in Prostate Cancer Today (IMPACT) meeting, which is held to disseminate the results of PCRP-sponsored research. Costs associated with travel to this meeting, up to \$1,800, should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research Supplies
- Equipment
- Purchase of datasets and/or databases
- Clinical research costs (other than costs for clinical trials, which are not allowed)
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings in addition to the required meeting described above.

The CDMRP expects to allot approximately \$2.4M of the \$80M FY13 PCRP appropriation to fund approximately 2 Population Science 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 two-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

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

A. Where to Obtain the Application Package

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

B. Pre-Application Submission Content and Form

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

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

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

- **Application Information – Tab 1**

- **Application Contacts – Tab 2**

- **Collaborators and Conflicts of Interest – Tab 3**

FY13 PCRP Integration Panel (IP) members should not be involved in any preapplication or application. A list of FY13 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel13>. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

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

- **Submit Pre-Application – Tab 5**

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

- **Other Documents Tab**

No additional documents are required.

C. Application Submission Content and Form

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

Grants.gov application package components: For the Population Science 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.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. *The inclusion of preliminary data to support the study feasibility is required.* Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application, including examples of previous successful collaborations (if applicable). *Provide the reasoning that supports why the proposed project is considered population science research.*
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely 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:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific review. Address potential problem areas and present alternative methods and approaches. Describe the statistical/analytical plan(s) for the research proposed. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples or datasets, including ethical and regulatory considerations. *This award may not be used to conduct clinical trials.*
- **Overarching Challenges and Focus Areas:** Describe how the proposed study is responsive to one of the PCRP overarching challenges. If the proposed project does not address any of the overarching challenges, provide a description to justify how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care. In addition, state at least one of the PCRP focus areas to which the proposed study is responsive.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.*
 - References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
 - Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.
 - Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work, to include:
 - Unique expertise,
 - Availability of and access to research resources, and/or
 - Availability of and access to appropriate prostate cancer populations.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.
 - Transition Plan: Describe the methods/practices that will be used to facilitate the adoption or utilization of the outcomes from the proposed project to make advancements in prostate cancer research and/or clinical care.

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

The technical abstract is used by all reviewers. Programmatic reviewers do not typically have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

Describe the proposed research project including the following elements:

- Background: Present the ideas and reasoning behind the proposed project.
- Objective: State the objective to be reached. Provide evidence or rationale that supports the objective.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design.
- Impact: Summarize the potential impact of the proposed project on the elimination of death from prostate cancer and/or enhancing the well-being of men experiencing the impact of the disease.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”

The lay abstract should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

- Describe the scientific objective and rationale for the proposed 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?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study to advancing the field of research?

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

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”
Explain in detail why the proposed research project is important, as follows:
Describe the short-term impact: Detail the anticipated 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 the long-term anticipated advantages that the new understanding may ultimately contribute to the goal of elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.
PCRP overarching challenges: Summarize how the proposed project addresses one of the PCRP overarching challenges. If the proposed project does not address any of the overarching challenges, provide a description to justify how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care.
- **Attachment 7: Human Subject Plan (one-page limit):** Upload as “SubjectPlan.pdf.”
 - Describe how the proposed study population is appropriate to study the hypotheses. Include potential issues regarding ethics, information privacy, and assessment of risk versus benefit of participation.
 - Describe the availability of this population, whether the PI and/or research team currently have access to this population, and how access to potential participants will be coordinated.
 - Outline the recruitment strategy and past successes for recruiting similar populations.
 - Describe how the proposed sampling strategy is appropriate for the study hypotheses, design, methods, and analytical/ statistical plans.

3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C., for detailed information. ***Note: Some of the items in this attachment may be made available for programmatic review.***

- PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

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

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

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 will result in application rejection.

E. Other Submission Requirements

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

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

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

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

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

B. Application Review Criteria

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria. Of these, Impact, Research Strategy and Feasibility, and Statistical Plan are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Impact**

- To what degree the proposed study could, *whether short-term or long-term*, make a substantial impact for men at risk for prostate cancer and/or men with prostate cancer and ultimately contribute to the elimination of prostate cancer death and enhancing the well-being of men experiencing the impact of the disease.

- **Research Strategy and Feasibility**

- How the scientific rationale supports the research project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- How well the PI acknowledges potential problems and addresses alternative approaches.

- **Statistical/Analytical Plan(s)**

- Whether an appropriate statistical plan, including sample size projections and power analysis, is present and adequate for the study.
- How the data analysis plan is consistent with the study objectives.

- **Human Subject Plan**

- How well the selected population is described and whether it is appropriate for the proposed project.
- How well the PI has demonstrated sufficient availability of and access to the appropriate prostate cancer population(s).
- To what extent the PI has supported the feasibility of accruing a statistically significant sample from the proposed population.
- To what degree the plan for recruitment is appropriate for the study's proposed hypotheses, design, methods, and statistical/analytical plan(s).
- Whether issues regarding ethics, information privacy, and assessment of risk versus benefit of participation have been adequately considered.

- **Personnel**

- Whether the PI meets the eligibility requirements for this mechanism.
- How 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 biostatistical expertise to support the project.

- 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:

- **Environment**

- To what extent 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 collaborative arrangements).
- To what extent the quality and extent of organizational support are appropriate for the proposed research.

- **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 make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

a. Ratings and evaluations of the peer reviewers

b. Relevance to the mission of the DHP and FY13 PCRP, as evidenced by the following:

- Adherence to the intent of the award mechanism
- Programmatic relevance in relation to the PCRP overarching challenges and focus areas
- Relative impact
- Program portfolio composition

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

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

C. Withdrawal

The following may result in administrative withdrawal of the application:

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

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

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

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

B. Administrative and National Policy Requirements

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

C. Reporting

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

D. Award Transfers

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

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance 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 Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Human Subject Plan (SubjectPlan.pdf) as Attachment 7.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	