

# Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

## Prostate Cancer Research Program

### Exploration – Hypothesis Development Award

**Funding Opportunity Number: W81XWH-14-PCRP-EHDA**

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

#### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), June 25, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, July 9, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, July 14, 2014
- **Peer Review:** August 2014
- **Programmatic Review:** October 2014

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

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

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2014 (FY14) Prostate Cancer Research Program (PCRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The PCRP was initiated in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY13 totaled \$1.29 billion. The FY14 appropriation is \$80M.

The mission of the FY14 PCRP is to find and fund research that will lead to the elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. Specifically, the PCRP seeks to promote highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; multidisciplinary, synergistic research; translational studies to support the fluid transfer of knowledge between bedside and bench; research on patient survivorship and quality of life; the next generation of prostate cancer investigators through mentored research; and research on disparities in the incidence and mortality of prostate cancer.

#### **PCRP Overarching Challenges (*revised for FY14*)**

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

- Develop better tools for early detection of clinically relevant disease
- Distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer
- Develop effective treatments and address mechanisms of resistance for men with high-risk or metastatic prostate cancer
- Develop strategies to optimize the physical and mental health of men with prostate cancer

#### **FY14 PCRP Focus Areas**

All applications for the FY14 PCRP funding opportunities are also expected to address at least one of the following PCRP focus areas:

- **Biomarker Development:** Qualification and validation of biomarkers for early detection of clinically relevant disease, prognosis, and 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 prognosis and progression of prostate cancer

## B. Award Information

The PCRP Exploration – Hypothesis Development Award mechanism was first offered in FY03. Since then, 2,184 Exploration – Hypothesis Development Award applications have been received, and 237 have been recommended for funding.

The Exploration – Hypothesis Development Award supports the exploration of highly innovative, untested, potentially high-gain concepts, theories, paradigms, and/or methods that address an important problem in prostate cancer. Results of studies conducted through this award may provide the scientific rationale upon which a new hypothesis can be based or initial proof-of-principle of an innovative hypothesis. This award is designed to provide investigators the opportunity to pursue serendipitous observations that may reveal entirely new avenues for investigation. ***Presentation of preliminary data is inconsistent with the intent of this award mechanism and is therefore strongly discouraged. However, logical reasoning and a sound scientific rationale for the proposed work must be described.***

The PCRP seeks applications from investigators from a wide spectrum of disciplines including, but not limited to, basic science, engineering, bioinformatics, population science, translational research, and clinical research. ***In addition, applicants are expected to address at least one of the PCRP focus areas and one of the PCRP overarching challenges.***

***Research involving human subjects is encouraged under this funding opportunity but is restricted to studies without clinical trials.*** Correlative studies associated with an existing clinical trial are allowed if they are determined to be no greater than minimal risk by the local Institutional Review Board (IRB) of record and the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO). Projects involving human subjects or specimens must be exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101(b)) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Additional information on the protection of human subjects and exempt or expedited review status can be found at <https://www.bids.tswg.gov/>. For definitions and other information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the electronic Biomedical

Research Application Portal (eBRAP) “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).

All investigators applying to FY14 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 Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section L.***

### **C. Eligibility Information**

- All investigators at or above the level of postdoctoral fellow (or equivalent) are eligible to apply for this award.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### **D. Funding**

- The maximum period of performance is **1** year.
- The maximum allowable direct costs for the entire period of performance are **\$75,000** 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 **1** year.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization’s negotiated rate agreement.

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

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Clinical research costs (for studies exempt or eligible for expedited review only)
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

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

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from federal agencies submit applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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

***The CDMRP expects to allot approximately \$2.4M of the \$80M FY14 appropriation to fund approximately 20 Exploration – Hypothesis Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.***

## II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

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

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

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

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

### A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-14-PCRP-EHDA.

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

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

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

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

- **Application Information – Tab 1**

- **Application Contacts – Tab 2**

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

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

FY14 PCRP Integration Panel (IP) members should not be involved in any preapplication or application. A list of FY14 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel14>. For questions related to IP members and pre-applications or applications, refer to Section [IV.C., Withdrawal](#), or contact the CDMRP at [help@eBRAP.org](mailto:help@eBRAP.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.

- **Submit Pre-Application – Tab 5**

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

### **C. Application Submission Content and Forms**

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

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

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

**Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s).** Due to the blinded nature of the review process, identifying or making references to the PI,

collaborators, or their organization(s) in the Project Narrative, List of Abbreviations, Acronyms, and Symbols, or Abstracts is prohibited and will result in administrative rejection of the application. In addition, the use of “I,” “we,” “our,” “this organization” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed, or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, or in any other way highlighting the names of the PI, collaborators, or their institutions, is prohibited and will result in administrative rejection of the application and preclude invitation to submit a full application.

Although required, the Statement of Work, Research & Related Budget, R & R Subaward Budget Attachment(s) Form (if applicable), Biographical Sketch, Previous/Current/Pending Support, and Project/Performance Site Location(s) Form will not be forwarded for peer review or programmatic review. These documents will be used for administrative purposes only.

**Grants.gov application package components:** For the Exploration – Hypothesis Development 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 (two-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.

*The Project Narrative will be available for both peer and programmatic review.*

Describe the proposed project in detail using the outline below.

- **Innovation:** Innovation should be the primary feature of the proposed study. Concisely state how the proposed project represents the exploration of a shift in paradigm, a new line of questioning, or an innovative methodological approach to an important problem in prostate cancer.
- **Relevance to the PCRP Goals:** Briefly describe how the proposed research is responsive to one of the PCRP overarching challenges and at least one of the PCRP focus areas.
- **Hypothesis/Rationale/Purpose:** State the rationale for the proposed research. *The inclusion of preliminary data is strongly discouraged.*
- **Objectives:** State concisely the specific aims and research strategy of the study. *This award may not be used to conduct clinical trials or studies that*

*are not exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).*

- **Methods:** Describe the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.
- **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 (five-citation limit): 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). ***Do not include URLs that identify the organization(s) of the PI or collaborator.***
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols. ***Do not include information that identifies the organization(s) of the PI or collaborator(s).***
- **Attachment 3: Technical Abstract (one-page limit; half-page is preferred):** Upload as “TechAbs.pdf.”

State the FY14 PCRP overarching challenge and focus area(s) addressed by the proposed research project. Clearly describe the proposed research in one paragraph including the hypothesis to be explored, the objectives, the innovative aspect of the research, and the relevance of the project to the FY14 PCRP mission of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease. ***Do not include information that identifies the PI, the collaborator(s), or their organization(s).***

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

State the FY14 PCRP overarching challenge and focus area(s) addressed by the proposed research project. Clearly describe in one paragraph, in a manner readily understood by readers without a background in science or medicine, the objective of the proposed research and its relevance of the project to the PCRP mission of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease. Describe the ultimate applicability of the research (e.g., type(s) of patients it will help, clinical applications). ***Do not duplicate the technical abstract.*** The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community. ***Do not include information that identifies the PI, the collaborator(s), or their organization(s).***

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Exploration – Hypothesis Development Award mechanism, use the SOW format example titled “SOW for Basic Research.” The SOW must be in PDF format prior to attaching.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., for detailed information.
  - PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
  - PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
  - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

#### **D. Verification of Grants.gov Application in eBRAP**

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

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

***submission deadline. Any other application component cannot be changed after the end of the application verification period.***

#### **E. Submission Dates and Times**

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

#### **F. Other Submission Requirements**

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

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

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

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

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, based on (a) technical merit and (b) the relevance to the mission of the DHP and PCRCP and to 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 process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>. ***For this Program Announcement/Funding Opportunity, reviewers at both tiers of review will be blinded to the identity of the PI, collaborators, and their organization(s).***

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

## B. Application Review Process

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

- **Innovation**

- To what degree the proposed concept is innovative.
  - Whether the project proposes new paradigms, challenges existing paradigms, or otherwise represents the exploration of a new line of questioning or an innovative methodological approach to an important problem in prostate cancer.
  - To what degree the proposed research represents more than an incremental advance beyond ongoing or published research.
- Whether the concept is untested (e.g., no direct preliminary data).

- **Relevance**

- To what degree the proposed research is relevant and important to eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

- **Research Strategy**

- To what degree the proposed research is supported by a sound scientific rationale.
- To what degree the experimental design and methodology are appropriate to address the stated objectives.

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

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

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

**a. Ratings and evaluations of the peer reviewers**

**b. Relevance to the mission of the DHP and FY14 PCRP, as evidenced by the following:**

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

### **C. Recipient Qualification**

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

### **D. Application Review Dates**

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

### **E. Notification of Application Review Results**

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

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of 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.
- The PI, collaborators, or their organization(s) are identified or referenced in the Project Narrative, References, List of Abbreviations, Acronyms, and Symbols, or Abstracts.
- Use of “I,” “we,” “our,” “this organization,” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed, or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, or in any other way highlighting (and therefore revealing) the names of the PI, collaborators, or their institutions.

### **B. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov.

During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

### **C. Withdrawal**

The following may result in administrative withdrawal of the application:

- A FY14 PCRIP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY14 PCRIP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel14>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or requests funding for, a clinical trial that is determined to be greater than minimal risk.
- Inclusion of studies that do not qualify for exempt status under 32 CFR 219.101(b) or expedited review (32 CFR 219.110 or 21 CFR 56.110).
- 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, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

### **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

### **D. Reporting**

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

### **E. Award Transfers**

Refer to the General Application Instructions, Appendix 4, Section M, 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 eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

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

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

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

Phone: 800-518-4726

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

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

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	